The Advisory Board on Radiation and Worker Health
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention

Summary Minutes of the Thirty-fifth Meeting
January 24-26, 2006

The Thirty-fifth Meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Board) was held at The Doubletree Oak Ridge, Oak Ridge, Tennessee, January 24-26, 2006. The meeting was called by the Centers for Disease Control and Prevention (CDC's) National Institute for Occupational Health and Safety (NIOSH), the agency charged with administering the ABRWH. These summary minutes, as well as a verbatim transcript certified by a court reporter, are available on the internet on the NIOSH/Office of Compensation Analysis and Support (OCAS) web site located at www.cdc.gov/niosh/ocas. Those present and who identified themselves included the following:

ABRWH Members: Dr. Paul Ziemer; Chair; Dr. Henry Anderson; Dr. Roy DeHart; Mr. Richard Espinosa; Mr. Michael Gibson; Mr. Mark Griffon; Dr. James Melius; Ms. Wanda Munn; Mr. Robert Presley; and Dr. Genevieve Roessler

Designated Federal Official: Dr. Lewis Wade, Executive Secretary

Federal Agency Attendees:

Department of Health and Human Services:
Mr. Jason Broehm, Ms. Chia-Chia Chang, Mr. Larry Elliott, Ms. Chris Ellison, Mr. Stuart Hinnefeld, Ms. Liz Homoki-Titus, Ms. Emily Howell, Mr. Ted Katz, Dr. Jim Neton, Mr. David Staudt, Dr. Brant Ulsh

Department of Labor:
Dr. Diane Case, Mr. Peter Turcic

Congressional Representatives: Ms. Elizabeth Howell, Ms. Livia Lam, Ms. Jennifer Stansbury

Contractors:

Oak Ridge Associated Universities: Ms. Kate Kimpan, Mr. Bill Tankersley

Stanford Cohen and Associates: Dr. Hans Behling, Ms. Kathy Behling, Mr. Joe Fitzgerald, Dr. Arjun Makhijani, Dr. John Mauro

Public Attendees: See Registration.

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Tuesday, January 24, 2006

Dr. Paul Ziemer, Chairman of the Advisory Board on Radiation and Worker Health, called the meeting to order noting that most members of this Board have been members since it began its series of meetings in January, 2002. Retiring members will be recognized later in the meeting. Present are three individuals recently named by the White House as new appointees to this Board: **Mr. Brad Clawson** from Idaho National Laboratory; **Dr. Jim Lockey** of the University of Cincinnati Medical Center; and **Professor John Poston** from Texas A&M University. They will be at the next meeting in April; today they are observing. **Dr. Ziemer** welcomed their participation.

Dr. Lewis Wade, the Designated Federal Official, introduced **Ms. Kate Kimpan**, the new Project Director for Oak Ridge Associated Universities (ORAU), who will be replacing **Dr. Richard Toohey**. She will serve as the principal ORAU contact to NIOSH. **Dr. Wade** thanked **Dr. Toohey** for his contribution.

Dr. Ziemer requested registration by all attendees and sign ups for today's public comment period. Although the Board does not deal with individual claims, NIOSH staff members are available to assist in answering related questions. The Chair deferred approval of the minutes until Board members receive and read them, with action likely be taken Thursday afternoon.

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Dr. Wade clarified conflict of interest issues and then gave context for the Y-12 discussions. Conflicts of interest are expected to exist on the Board as it is comprised of people with valuable experience at the sites in question. Board members with conflicts for the Y-12 site profile are **Dr. Roy DeHart, Mr. Robert Presley** and **Mr. Mark Griffon** -- **Mr. Griffon** only when there are issues pertaining directly to the Atomic Trades and Labor Council. The policy with regard to conflict of interest on site profiles allows conflicted Board members to participate in table discussions but prohibits their making or voting on motions.

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Y-12 NATIONAL SECURITY COMPLEX
SITE PROFILE DISCUSSION/PLAN OF ACTION

Mr. Joe Fitzgerald,
Sanford Cohen & Associates

Mr. Fitzgerald presented an overview of the issue resolutions for the Y-12 site profile, one of the first profiles to be reviewed by the Board's contractor. The review is aggressive. Of particular urgency is the site profile technical issues relating to a subclass of workers: steamfitters, pipefitters, and plumbers who worked from October, 1944 through December, 1957. The Board desires to bring a timely resolution to that portion of a pending SEC petition. This Board earlier recommended approval of a petition for Y-12 employees who worked in uranium enrichment or other radiological activities from March, 1943 through December, 1947. The Secretary of the Department of Health and Human Services (HHS) has acted positively on that recommendation. The Board intends to resolve these technical issues and bring the portion of the petition that has not been acted upon to a vote at the April Board meeting.

Mr. Fitzgerald urged resolution of remaining issues so the Board will have necessary guidance and technical support for making a decision on the petition. He gave a chronology of Board, SC&A and NIOSH interactions aimed at narrowing issues and differences and producing resolutions. These entities have been meeting or conferencing almost monthly with robust analysis and data-gathering in the meantime. Key issues for both the SEC petition and the site profile reviews begin with data validity or reliability to assure that data used for dose reconstruction can be validated as representative of the plant, time period and processes. SC&A and NIOSH have not given up on obtaining some data from the files in Atlanta or elsewhere which might give a better handle on this issue, but so far the search has not proven fruitful. Various compensatory sources can provide some measure and test of consistency. Reliability of data is essential to the issue of adding a class to the Special Exposure Cohort.

A second issue is that the scope of review for the site did not narrowly consider Y-12 to be a uranium plant. Y-12 is one of many Department of Energy (DOE) sites with a diverse history including numerous activities with Cyclotron and Calutron in terms of generating different radioisotopes, handling plutonium -- in short a number of sources of radiation other than uranium. The focus now is how that may have contributed to the overall source term for the plant. The implications are important in the SEC petition context, as the class of workers in question may have moved throughout the plant and been exposed to non-uranium sources. SC&A is concerned about the lack of

any database to help clarify this issue. NIOSH is making available this week 6,000 pages of bioassay data from the X-10 side of the plant which can inform this analysis for identifying an appropriate coworker model. However, even if the bioassay data proves to be reliable, it will not answer all questions. As regards SEC petition consideration, resolution of this issue would assure that all the sources were accounted for in relation to this mobile worker class which includes pipefitters, plumbers and others.

Regarding job functions, NIOSH has provided immensely helpful information for determining dose distribution by virtue of job titles and categories. SC&A finds difficult to accept that the population under consideration is homogeneous with similar exposures. Instead, the exposure potential is actually higher than the average, a broad mean somewhere between 50 and 95 percent which needs continued examination. The working group has had good discussions about what the data indicates. The most useful practice is to actually look at the data and determine if the 50th percentile is appropriate or perhaps to take a more conservative approach and handle certain job categories separately. This determination could be facilitated with information on departments. While this matter may not be primary for upcoming discussions or the SEC petition, it is important for dose reconstruction.

Next, **Mr. Fitzgerald** moved on to three action items that SC&A took from the January 5th workgroup meeting.

1. The first item was to review factors used in Table 5-2 through 5-8 dealing with parameters on recycled uranium, with more on that later.

2. The second item was the 147 dose records from monitored workers used in the regressive statistical analysis and whether in fact that model was representative. This analysis took data from the 1960's and applied it to the 1950's for which data is sparse.

Dr. Ziemer paused the presentation to notify Board members that comments on January 19th were distributed via e-mail. Those comments will be made available today to the public.

3. The third action item was the OTIB-51 which deals with how to arrive at correction factors for early NTA film and angular dependence so that dose estimates can be accurately determined. Those comments were provided on the 19th. This issue was raised not only for the Y-

12 site profile but also during the past three reviews worked on by **Dr. Hans Behling** and **Ms. Kathy Behling**. It would be a fundamental step forward to have OTIB-51 contain this information and provide these factors. He said the approach is sound but the analysis should be run for energies beyond 700 keV; 800 and 900 offer other benchmarks and it might be appropriate to have additional curves provided. This is a loose-end issue. The chemical operators were appropriately considered in the analysis but whether by oversight or intention were not cited in method two, and he would like to find out about that. The OTIB did not address some issues relative to neutron flux below the NTA threshold. Site-wide workers at Y-12 may have been exposed to those thermal neutrons. The preceding are very specific technical comments. **Mr. Fitzgerald** expressed general support for the approach provided in the OTIB.

4. Also of note is the action item concerning revisiting the tables in the TBD for Y-12 dealing with recycled uranium. Comments center on whether one can be very generic or whether current data would support generation of more tailored information for particular operations and processes. He also raised the question on whether badging was based on maximum exposure workers. Although SC&A hasn't seen the 147 dose records, they are beginning to go through the expanded CER database through 1965. They feel that some of the lower numbers just below 1,000 millirem per quarter suggest a group of workers who may not have been maximally exposed in the early period. There are appreciable differences in the numbers at the pre-criticality/post-criticality juncture. The data is not conclusive but does suggest that a sub-group of workers who were not badged may have been maximally exposed or there may have been cohort badging in certain activities. This issue is similar to one relative to bioassay and whether one can be assured that this is not random sampling on a department-wide basis. SC&A will focus on the reliability, robustness and applicability of the 6,000 pages of X-10 data. Along with NIOSH, they will examine what the data suggests to determine whether U-233, radon and other nuclides elsewhere in the plant would be significant in helping answer that question and in corroborating the reliability of the electronic database. The review calls for clarity in determining whether or not the basis for coworker models and the maximally exposed individuals can be established.

In SC&A's view, everything else is clearly appropriate for a site profile. The detailed review contains over 100 findings, many of which are factual accuracy and technical issues not likely to bear on the SEC petition determination but important enough to be second priority.

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Discussion began with **Mr. Griffon** seeking clarification from **Dr. Jim Neton** about the availability of a disk for SC&A and the Board. **Dr. Neton** will try to have an answer by the end of the day to expedite release of the disk. **Dr. Ziemer** said the document will be made available to the public before long. **Dr. Henry Anderson** then asked about whether a portion of the 6,000 records will be abstracted or by what means this information will be provided in a timely fashion. **Dr. Neton** said that not having seen the 6,000 records, he did not know, but the concept was that these records include data for radionuclides other than uranium, specifically plutonium and possibly polonium. NIOSH intends to gather enough data make a robust coworker matrix to apply to workers at processes such as the Calutron and the Cyclotron and other operations involving non-uranium activities, provided identification can be made of who was monitored for those nuclides. In addition to these 6,000 records, NIOSH is looking at Department 4000 records from the X-10 facilities. Those are people who worked on operations at Y-12. These two datasets may provide the basis for some quality analyses that would allow dose reconstructions for non-uranium radionuclides at Y-12. **Dr. Anderson** asked for a time frame. **Dr. Neton** replied that ORAU is currently reviewing the data, then it will be decided if the data can or cannot be used in a timely manner.

Dr. Ziemer next reminded the Board of the conference call scheduled for March 14th. One of the items will be an update on the status of these issues for the Y-12 SEC petition and pertinent issues. At that point the Board must determine if it will be ready to have a vote on the petition for the April 25th through 27th full Board meeting.

With issues fresh in mind and all parties present, **Dr. Wade** wanted to make detailed plans for interactions between NIOSH and SC&A to ready the vote on an SEC petition at the end of April. **Mr. Robert Presley** found problematic the SEC petition's mentioning of only pipefitters while leaving out large groups of workers who had likely worked with uranium issues, such as machinists and chemical workers, particularly considering that Y-12 was ramped up from a chemical operation into a production operation at that time. **Mr. Larry Elliott** clarified that the current language is only a starting point based on a definition put forward by the petitioner. During evaluations of petitions, the definition tends to expand to cover other site workers who should be considered in that class. He echoed the importance of resolving these issues because it goes directly to the first prong of the two-pronged test for considering adding a class - can dose be sufficiently reconstructed for that class.

Dr. Ziemer asked if the job categories or individuals from Y-12 during the time period are well known, perhaps well established in the work records. **Dr. Wade** clarified for the record this discussion resides in

the context of the site profile evaluation. **Mr. Presley** said that in the past four or five years examining records he has come across a tremendous amount of job description material. He said **Dr. Neton** has a list up to 60 pages long in which the information exists to properly categorize jobs. **Dr. Neton** said the working group is aware of having a title for almost every exposure measurement in these exposure records; however, the titles were not standardized, so ORAU has made judicious choices in collapsing these data down from hundreds to perhaps 40 relevant job types. **Dr. Neton** also noted that the monitored workers seem to have been the more highly exposed. **Mr. Griffon** said that despite having job titles and work locations, a cross-link of where they worked is lacking. These possible multiple exposures might still be covered in a blanket distribution type model, but that level of detail is not currently available. **Dr. Neton** affirmed **Mr. Griffon's** statements and said NIOSH is getting near the proof of the principle that these job categories can be collapsed. It will be difficult to decide who was potentially exposed to the non-uranium operations. If such workers cannot be binned into the right categories then the usual assumption that they could have been exposed will apply. These decisions can be made; the primary task is to identify how the group will go about it. These considerations are seen in the comment resolutions in the matrix - how NIOSH will use the 95th percentile, which categories of workers will go in there and specifics on the nuts and bolts of how this will be accomplished.

Dr. Wade highlighted the importance of framing those nuts and bolts issues because this will be the Board's last chance to instruct the principles in terms of the degree of specificity sought. **Mr. Griffon** requested a few more examples from NIOSH on how the dose reconstruction models are applied to different situations, now that the working group has more data about other radionuclide issues. **Dr. Wade** and **Dr. Ziemer** agreed that this can all get done. **Dr. Neton** said he totally agrees with **Mr.Griffon** on the need for more examples. He also wanted make several points. Voluminous records exist for uranium urinalysis, film badge results and TLDs, and it will be a key task to establish the credibility or reliability of these datasets.

Furthermore, although the presence of non-uranium nuclides must be considered, they were not routine operations and did not involve a major percentage of the workforce, despite the focus that issue is receiving.

Thirdly, **Dr. Neton** wanted to be clear that the 6,000 page set of information is not full records but bioassay data, some full pages and some nearly blank and possibly some redundant pages. He did not want people's expectations for this information to be too high.

Mr. Griffon commented that NIOSH had done at least a cursory analysis of the claimants and determined that about ten to 12 percent would rely on urinalysis records for dose reconstruction, whereas the other 88 percent would rely at least to some extent on the coworker models. **Dr. Neton** continued, explaining that the further back one goes before 1961, the more sparse the data. That means fewer and fewer samples are available thus necessitating the use of coworker data, which spotlights the issue of which percentile to use for coworker data. Whether to use 50^{th} or 95^{th} percentile is a matter of detail for the dose reconstruction process as opposed to something that would prevent doing a dose reconstruction at all. It is a matter for the working group.

Dr. Ziemer expressed concern that the working groups remain ad hoc groups rather than becoming institutionalized as committees. He then asked the current working group to continue on the Y-12 site profile as it relates to the SEC petition, specifying along with **Dr. Wade** that the task relates only to the site profile, and working with SC&A and NIOSH in the resolution of identified issues. **Dr. Ziemer** asked the working group to make preparation for both the upcoming conference call and the next meeting. He asked **Mr. Griffon** to work out a schedule for the working group, NIOSH and SC&A.

Dr. Wade noted that the upcoming suite of working group meetings would need to be available to representatives of the petitioner and those people who have a particular interest in these matters. **Mr. Presley** asked if the site profile is to be considered from 1944 to 1957 or 1943 to the present. There are years beyond 1957 that he feels should be looked at. **Dr. Ziemer** said the petition itself covers 1944 to 1957, period. **Ms. Munn** felt the site profile should run from initial operations to the current date, although the immediate priority would be those questions affecting the period of time covered by the SEC petition. **Dr. Wade** emphasized that the working group will only be looking at the site profile, even though they are likely to focus on certain areas for reasons of the SEC petition. Their task is the site profile review, not an SEC petition activity. Otherwise, the workgroup would have to be reconstituted. **Dr. Ziemer** said to proceed on that basis.

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PROCEDURES FOR BOARD EVALUATIONS OF SEC PETITIONS DISCUSSION, PART I

Dr. James Melius, Chair
Special Exposure Cohort Review working group

Dr. Melius presented the revised version of the January 9th conference call report on SEC petition procedures along with subsequently collected comments from the Board. The working draft report was produced from **Dr. Wade's** outline of a half-day November workgroup meeting in Cincinnati with **Dr. DeHart, Mr. Griffon**, **Dr. Ziemer** and **Dr. Melius** along with several members of NIOSH staff. The purpose of this working group report is to streamline the petition evaluation process, particularly steps three and four. Comments of other Board members and the public are welcome following the presentation.

Dr. Melius noted this is a simplified schematic of the steps in the petition process. First, the SEC petition is sent to NIOSH. Secondly, the petition is reviewed to see if it qualifies, and thirdly, after it has been accepted and deemed appropriate for follow-up, NIOSH does an evaluation of the petition to determine if it meets SEC requirements to be a member of the cohort. Fourthly, the NIOSH evaluation report is transmitted to the Board for review. In simple terms, based on its review, the Board then makes a recommendation to the Secretary on whether or not to accept that group as a class into the Special Exposure Cohort.

The workgroup had focused on steps three and four, namely how NIOSH conducts its evaluation of an accepted petition and how the Board reviews that evaluation. Their goal was to clarify the steps and increase efficiency because the petition process has required several meetings for deliberations and much work in between meetings to reach conclusions. They first focused on the steps from evaluation to recommendation, making the assumption for purposes of this report that the current regulations regarding the SEC qualifications stay in place. The main task at hand was to clarify the criteria and the procedures the Board would use in reviewing the NIOSH petition evaluation report to expedite the process without compromising the scientific basis.

The workgroup arrived at four considerations. One: timeliness, so petitioners would not have to wait too long for a review and to reduce the Board and NIOSH's time and effort. Second: fairness, to ensure each petition gets due effort in evaluation and review. Third: criteria understandable for the public and everyone involved. Fourth: consistency, or application of the same criteria to each petition to ensure equal treatment for all sites.

A key point is that these evaluations focus on exposure data sets, such as biological testing and external radiation sources collected over a period of time. The workgroup dealt with how to evaluate the credibility and validity of each data set in question. To that end they concern themselves with pedigree of that data, its quality, how it is generated; the methodology, whether up-to-date or not and how methods from 50 years ago compare to current ones; how to assess quality control from decades past and monitoring methods which were under development, and the relationship of the data under consideration to other sources of exposure information about the facility or the workers. Although some of these data sources may not be as comprehensive as the set intended for current use in individual dose reconstruction, the data need to point to the same thing.

Internal consistency is needed. The basic dataset needs to make sense based upon what is known about the facility's operations as well as the methods used for monitoring. Another key consideration is the representativeness of the data and whether they cover all areas of the facility. Monitoring in only one portion, for example, may not be applicable to exposures elsewhere in the facility.

This group is also interested in whether the data adequately cover all time periods of interest in the petition and whether the dataset can be used to calculate individual doses during a given time period or are there gaps in data. Much time is spent trying to figure out the time span fairly and reliably covered by particular datasets.

Another point of focus concerns whether the dataset can be generalized or used to cover mobile workers with varied tasks. If it does not, there are options in terms of splitting up the Special Exposure Cohort or accessing other appropriate datasets. The group also put focus on subsets of the data and how robust the data can be as it gets broken down into smaller and smaller subsets.

Regarding data, **Dr. Melius** said the use of several different sets of data is usually not simple. There is a need to be able to focus on key sets of data critical to assessing whether or not individual dose reconstruction can be conducted reasonably within the constraints of timeliness, accuracy and fairness to the exposed workers. Feasibility points to readily available data. Timeliness requires access to the data and calculations necessary to do dose reconstruction without waiting years. Fairness requires that NIOSH demonstrate not only the ability to dose reconstruction but also the ability to appropriately reconstruct doses for all the different groups covered under the Special Cohort petition or evaluation.

Additionally, in recent evaluations of Special Exposure Cohort reports NIOSH has been asked for sample dose reconstructions using actual representative data. These demonstrations show that it is possible to do dose reconstruction for the various groups involved. The workgroup report contains further discussion to try to set out the criteria for this.

The report also recommends a couple of procedural changes. One is that NIOSH provide a mid-point evaluation done after the petition has been certified. Currently, as soon as a petition is qualified, NIOSH prepares a very general report on their plans for doing the evaluation. It is general because NIOSH has not had time to look at the different datasets. A more detailed evaluation plan later in the process would be helpful both for NIOSH and the Board in reviewing the evaluation. This mid-point report could specify what datasets and types of information were going to be critical in assessing whether or not dose reconstruction is possible or whether the group would qualify to be part of the Special Exposure Cohort.

A second recommendation, whenever possible, would be to complete a site profile before evaluation of a petition from that site, or at least review relevant portions of the site profile, because that information is very helpful in resolving issues about the petition evaluation. Admittedly, this must be done on a case by case basis. The Board's contractor could also be asked to follow a procedural approach appropriate for the Board's review of the SEC petitions, thus increasing efficiency and fairness.

Dr. Ziemer asked Board members for questions, comments or concerns about the document. **Dr. DeHart** wanted to be sure the public understands that an SEC petition could be divided and sub-grouped so that one group would be certified and another group would wait for determination on calculation of dose. **Dr. Melius** added that even within the petition the groups could be sub-grouped; in fact that has already been done by demarcating different time periods of exposure, and NIOSH already does this to some extent.

Dr. Wade offered comments. Tomorrow, SC&A will present recommended procedures for the Board to follow which will mesh well with today's discussion. SC&A will also report on its initial review of NIOSH's procedures in terms of reviewing the SEC petitions, so that will inform the discussion. He reminded the group that they're an advisory committee to the Secretary of HHS, and when he briefed the Secretary's advisors on the agenda for this meeting, they were very interested in this item in particular and had some thoughts to share. They do want to give this important issue a full vetting. They want to be sure incoming Board members have an opportunity to participate in this

process by which they will be governed. He suggested that as background for this discussion he can ask counsel tomorrow to address what timeliness means in the context of the Rule and of the law and applauded the working group's willingness to work on this very important issue.

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INDIVIDUAL DOSE RECONSTRUCTION REVIEWS (SETS 1, 2 AND 3)

Dr. Hans Behling,
Ms. Kathy Behling,
Sanford Cohen & Associates

Concerning the first set of 20 cases, **Ms. Behling** reported that all have been reviewed and put through the full resolution process. She was not sure if the Board had any final issues to be addressed, although she believed there was a discussion point on a possible letter for the HHS. The report on the second set of 18 cases has been submitted, Board meetings have been held, and the working group met with NIOSH to discuss the associated findings. SC&A was hoping to get the written responses from NIOSH prior to this meeting but these have not yet been reviewed. For the third set of 22 cases, SC&A has submitted a draft report and held a conference call with the assigned Board members. Changes based on those comments have been made and SC&A's matrix regarding the associated findings was recently submitted to the Board and NIOSH.

Currently SC&A is nearing completion on the fourth set of 20 cases. **Ms. Behling** said SC&A is hoping during this meeting to establish a more efficient process of sending out individual reports with the assigned Board members and having discussion with them prior to publishing the report. SC&A will possibly be in a position to set up those meetings the second week in February.

Ms. Behling offered an overview of the third set for the benefit of new Board members and as a reminder to all present of the stops involved in the dose reconstruction process. First, SC&A looks at the data studied by NIOSH and ORAU. They take NIOSH's Interactive RadioEpidemiological Program (IREP) input sheets and attempt to reproduce the doses. If they can't reproduce all the doses, they do a spot check or a selection, a process to be detailed later on today.

In addition to reconstructing the dose, SC&A examines whether or not the dose reconstructor correctly used, understood and applied the

appropriate procedure. They try to ensure that the regulations and assumptions used in the dose reconstructions are fair, consistent, well-grounded, and based on the best available science.

Lastly, they check to see if all the data received and looked at by NIOSH appears on the Computer-Assisted Telephone Interview (CATI) report. They want to ensure that all the Department of Energy (DOE) records and any monitoring and bioassay data is being used to address all aspects of activity submitted by the claimant. For example, for the third set of cases, 20 of the 22 cases were considered advanced reviews. Looking at the CATI report enabled SC&A to make a determination and suggest areas in which SC&A and NIOSH could or could not expand on the information available.

Ms. Behling noted that confusion abounds over the issue of which procedures are being used and how the entire dose reconstruction process goes forward. She explained that for dose reconstruction, it is first looked at by a group at ORAU that makes a determination based on the cancer and a preliminary look at the dose to fit it into one of three categories:

#1Minimized dose reconstruction, which for the sake of efficiency does not have to calculate the entire dose because there is sufficient dose to put the individual over the 50 percent POC;

#2The maximizing approach, most common in these 60 cases, where the dose reconstructor uses a set of procedures specific to that case and situation in attempt to show that the claimant does not go over the 50 percent POC even when receiving all the benefit of the doubt;

#3and the last approach, to be covered by **Dr. Behling** at the end of this presentation, the best-estimate dose reconstruction.

The fourth set of reviewed cases exemplified some true best-estimate dose reconstructions. NIOSH looks at all the records to make a painstaking and very detailed assessment for internal and external. Using IREP summary sheets to reproduce doses for these best-estimate cases has become much more tedious for SC&A reviewers due to the computer programs and workbooks used by the NIOSH dose reconstructors.

Ms. Behling next broke down the categories of types of information used in the SC&A review checklist. For data collection issues they review whether NIOSH did get all the data they requested from DOE and had enough data including external, internal and CATI information to adequately complete this dose reconstruction. Misinterpretation of procedures is the root cause of 30 percent of the findings. Currently

ORAU is using the workbook dose reconstruction tools which provide an easier, much more efficient and consistent dose reconstruction approach than ever before. Many of the findings will be eliminated or at least reduced when the workbooks are used almost exclusively.

Under Task III SC&A has begun to look at the workbooks and **Ms. Behling** noted it will be critical in the future to ensure that the workbooks are appropriately using the information in the procedures and in the Technical Basis Documents. The statistics on these 60 cases largely stays the same as last time, even given a few minor calculation errors, procedures not referenced and similar problems early on within the third set of 22 cases. The only significant change in statistics arises where, as reviewer, they could not reproduce the dose. In earlier findings that number was two percent, and now the number is 14 percent. When SC&A encountered for the first time a best-estimate done for the external dose, it raised many questions. SC&A didn't know the dose reconstructor was using a workbook and the reviewer ultimately was unable to reproduce a lot of information there, which raised the statistic.

Dr. Ziemer asked what number of findings would have resulted in a change to the compensation of a worker. **Dr. Behling** said that of all 60 cases to date, he could say with a high degree of certainty that not one of them would be changed. **Ms. Behling** elaborated on an earlier comment that much conservatism is built into these maximum dose reconstructions and that reassessments for neutron doses will be based on best-estimate procedures rather than ORAU TIB 2, 8 and 10. The benefit of these 60 cases has been to give the dose reconstructor the option of doing the dose reconstruction manually, using the aforementioned procedures. This process facilitated part of Task III, to identify where the procedures are unclear and complex. NIOSH has conceded they will try to clarify the procedures, which will address the finding concerning misinterpretation of procedures in 30 percent of cases.

Dr. Behling summarized what they have learned to date. Having reviewed almost all of the four sets, they can conclude that most of the audits were maximized, assigning far more dose than would reasonably have been received. Only a few cases involved partial dose reconstructions needed to get over the 50 percent mark. The impact of findings concerning a deficiency, a few missed doses, is overshadowed by the huge dose that has been assigned. It comes to the point where in context with these errors one approaches or exceeds 50 percent and NIOSH has recourse to say the gift is coming back.

Nevertheless, these findings do point to things which need to be looked at for the sake of process credibility. It does not look right

to continuously commit the same errors even if they are marginal errors with no impact. The checklist has made that clear; the reviewers do not anticipate anything that would potentially have converted a non-compensable to a compensable case.

For the first time, **Dr. Behling** said, we have encountered the best-estimate methodology, which is impressive for its detail and complexity. It must be very tedious for the dose reconstructor who must actually model and assess a volume of records decades in the making. That is time-consuming for the dose reconstructor and the reviewers. Now, best estimates are usually invoked in situations where the potential exposures will lead to a POC of between 45 and 50 percent. This calls for great care in looking at every aspect of the dose reconstruction process, because there is no buffer.

SC&A will not do the POC calculation. That will go back to NIOSH. However, there will be some instances of 48 POC and the findings will be dangerously close if not over that limit. SC&A will not proceed beyond the point of identifying these findings. Dose audits are at a new position wherein more and more best estimates will be used, requiring much more detailed scrutiny for the assessment. The use of workbooks has all but eliminated many of the errors found under the min/max approach. They are extremely useful and relatively easily audited. Their use of computer codes--Crystal Ball-- to calculate uncertainty will eliminate many of the concerns found in the first 60 cases, where few people could understand the procedures for determining uncertainty. **Dr. Wade** thanked them for their presentation.

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In the brief comment period afterward, **Dr. Ziemer** and **Dr. Wade** ascertained that NIOSH has provided responses on cases 21 through 30 but nothing beyond that so tomorrow the workgroup will place a different course of action for each of the 20 sets, bringing them to resolution and closure. **Dr. Ziemer** announced the public comments period will start an hour earlier than scheduled but assured everyone that it would still be in session at the designated start time of 5:30 p.m. today.

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PUBLIC COMMENT PERIOD

Dr. Ziemer offered remarks and ground rules. He called for concise comment and said the Board is seeking to identify if the system is working well and where fixes are needed. He reminded the public that this Board does not do the dose reconstructions or determine who is eligible for compensation, nor does it review denied cases. This is not an appeals board. Its well-defined responsibilities include reviewing the work of NIOSH to ensure adherence to proper procedures. For detailed concerns about an individual case, members of the public can talk to NIOSH people who are available here today to provide or obtain information and answers. **Dr. Ziemer** then took public comment in the order of the sign-ups.

The following is the list of the members of the public who spoke. A full transcript of the public comment is available on the OCAS web site, www.cdc.gov/niosh/ocas.

Mr. Larry Jones, ATLC health and safety representative, Y-12; Ms. Barbara Walton, Bethlehem Steel survivor; Ms. Kathy Bates, daughter of survivor; Ms. Janet Michele*, Coalition for a Healthy Environment and the Alliance for Nuclear Worker Advocacy Groups; Ms. JoNell Barton, claimant; Ms. Doris Henline, claimant; Ms. R. L. Ayers, survivor; Mr. George Eldridge, survivor; Mr. Gary Foster, son of claimant; Mr. Forrest Johnson, claimant; Mr. Kenny Cook, ATLC; Ms. Eliza Robinson, claimant; Mr. Bob Warren, claimants; attorney; Ms. Beulah Lindsey and Mr. Alvin Lindsey, survivor children; Mr. Glenn Bell, Chair, Y-12 Chronic Beryllium Disease Support Group; Mr. Richard Miller, GAP.

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With no further comments, the Board officially recessed until the following morning.

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Wednesday, January 25, 2006

Dr. Ziemer welcomed all to day two of the Advisory Board on Radiation and Worker Health in Oak Ridge, Tennessee, encouraging registration of attendance and sign ups for the public comment period at 7:30 tonight. Copies of today's documents are available in the room. Board members should have received copies of minutes of the August and October meetings which will be reviewed tomorrow. **Dr. Wade** thanked the Board for its difficult work and commended the high level of transparency, which reflects well on the quality as well as the quantity of the work.

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PACIFIC PROVING GROUNDS SPECIAL EXPOSURE COHORT

No conflicts of interest on the Board were announced concerning the petition for Special Exposure Cohort by the petitioners for the Pacific Proving Grounds. **Ms. Daniella Karo**, representing the petitioners, was present via telephone, and **Dr. Paul Blake** was also present on behalf of the Defense Threat Reduction Agency (DTRA) which is involved in a counterpart program concerning compensation for atomic veterans. Board members were provided a recent document containing comments and concerns raised by DTRA to be discussed in connection with this petition. **Dr. Wade** added that **Dr. Neton's** presentation will be proof that there are no simple SEC petitions.

Dr. James Neton,
NIOSH/OCAS

Dr. Neton addressed the evaluation of SEC Petition No. 20, received by NIOSH under a different definition. NIOSH is now evaluating the Pacific Proving Grounds in total and not just Operation HARDTACK 1, which was the basis for that petition. The Pacific Proving Grounds is a series of atolls and islands in the Marshall Islands where the U.S. military conducted a series of nuclear weapons tests from 1946 to 1962, starting with Operation CROSSROADS and ending with DOMINIC. The petition received by NIOSH, initial class, was for all scientists and couriers employed at Enewetak Atoll during Operation HARDTACK from July 1st, 1958 through August 31st, 1958 -- a very narrow window of time. As is usual with petition evaluations, NIOSH looked beyond the established class to see if any additional exposure scenarios and time periods should be evaluated and possibly covered under the petition.

Following the procedures and guidelines established by 42 CFR 83, the Special Exposure Cohort rule, a petition for SEC status was submitted for Pacific Proving Grounds and was qualified on April 11, 2005. The petitioners and the Board were notified, and a Federal Register notice was published on May 5, 2005. The NIOSH evaluation of the petition is summarized in their report of October 20, 2005, sent to both the petitioners and the Board. On January 18, 2006 a Federal Register notice advised that the report would be discussed by the Board at its upcoming meeting.

In December **Dr. Blake** had written NIOSH expressing his concern that several misrepresentations in a Nuclear Regulatory Commission (NRC) report on DTRA's program may lead to misconceptions by NIOSH about the operating status of said program. On January 20 NIOSH filed a

supplement to their evaluation in which they attempted to address the issues raised and to slightly narrow both their proposed class definition and the focus of the petition.

Dr. Neton reported that the required steps in the evaluation process included the application of the two-pronged test for feasibility and health endangerment. He described the types of data reviewed in determining feasibility, including the availability of resources. He explained the results of such efforts in determining if there were sufficient sources of ionizing radiation and how these sources were delivered in concluding whether workers' health could have been endangered through such exposures.

NIOSH conversed by phone and later shared a site visit with DTRA personnel engaged in a similar program of dose reconstructions for military personnel who were at these test sites. NIOSH evaluated DTRA's process for possible use in reconstructing doses for purposes of Energy Employees Occupational Illness Compensation Program (EEOICPA.) DTRA's example dose reconstructions used the ICRP-30 models for internal dose and estimated a 50-year committed dose rather than the annual doses NIOSH uses under this program for IREP calculations. **Dr. Neton** also noted that dose reconstructions for the DTRA's Nuclear Test Personnel Review program are conducted for non-presumptive cancers.

As for affidavits and documentation provided by the petitioners, there was no monitoring for internal exposure from ingestion or inhalation during these time periods and no evidence to link the considerable external data to internal exposure. NIOSH could not find bioassay sample records from Operation CROSSROADS, and the quality and reliability of that data was questioned in the publicly available records, as these measurements were done on board ship with available survey instruments, with no long-range plan for measurement. Data for off-site air sampling was insufficient to enable dose reconstruction for workers, as they were primarily environmental samples related to possible civilian exposures.

When NIOSH found nothing available for bioassay sampling and the environmental monitoring data was insufficient, they looked to DTRA's approach of using a sophisticated computer program to estimate internal dose from external dose results on the badge. However, in considering this whole program, NIOSH recognized that a lengthy 2003 review by the National Research Council questioned the credibility of the upper bounds raised and the reliability of the methods. Although the NRC review did not invalidate the model in question, it raised questions about the multiple sources of uncertainty and whether the method is valid for making these assumptions.

Dr. Neton noted that in NIOSH's review they were evaluating DTRA's program only for purposes of reconstructing doses with sufficient accuracy under EEOICPA. They were not questioning DTRA's ability to reconstruct doses for their own program. That finding and numerous others, however, indicated that doses could be either underestimated or overestimated, but the report made no real indication of the magnitude of corrections or the uncertainties in either direction, so sufficient accuracy cannot be assured.

DTRA's plan of action to evaluate these issues and complete their analysis was slated for June 2006. Although interim guidance issued July 16th allows DTRA to move forward with dose reconstructions by multiplying the internal doses by a factor of ten, NIOSH has not seen scientific analysis of that approach and feels it would not constitute sufficient accuracy under the requirements of this program.

NIOSH then revised the class definition from covering Operation HARDTACK 1 to all employees of DOE, DOE contractors or subcontractors employed there from 1946 through 1962 who were monitored or should have been monitored for exposure to ionizing radiation as a result of nuclear weapons testing at the Pacific Proving Grounds.

Sources of internal exposure from multiple detonations resulted from fallout contamination rather than direct exposure to the criticality event. Even though NIOSH believes health was endangered due to accumulated internal exposures through episodic intakes of radionuclides, they lack access to sufficient bioassay or air monitoring to properly estimate doses.

Discussion ensued with **Dr. Ziemer** and **Dr. Neton** clarifying points. Some dose reconstructions were completed from this newly-defined class of 65 but under SEC regulations it turns out they lacked sufficient accuracy.

Concerning DTRA's suggestion of missed data sources, **Dr. Ziemer** asked if those new bioassay sources would be readily available at least for determination of usefulness. **Dr. Neton** said he'll defer that question to the Department of Labor (DOL.)

Dr. Melius questioned how an operational determination will be made regarding the SEC definition involving a "monitored or should have been monitored." **Dr. Neton** explained that NIOSH held discussions with the DOL and decided to narrow the class of workers to those fitting this description who were actually exposed. Otherwise, site employees who did not even work in the presence of radioactive materials would be eligible.

Mr. Peter Turcic from the Department of Labor said the provision, present in all Congressionally-mandated SECs, is handled for all sites by occupation. The exception was Amchitka where it was handled by policy.

Mr. Griffon asked if the DTRA case reviewed by NIOSH included internal dose estimates and whether those models could not credibly bound doses for claimants in this population. **Dr. Neton** replied that based on the NRC review questioning the reliability and uncertainty of the method, NIOSH determined that DTRA's models could not bound the internal exposures with accuracy sufficient for this program.

Dr. DeHart wondered, given the 65 case definitions and perhaps 1,000 civilians involved, if there has been any active program to notify or contact prior workers. **Dr. Neton** did not know of any.

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PETITIONERS RESPONSE

Ms. Daniella Karo, petitioner

Ms. Karo indicated she had no presentation per se but, having read the evaluation, she did have questions to ask. She wanted to know how Congress came up with an upper limit of 250 days of exposure needed to establish this kind of class, why Amchitka Island employees were not held to this requirement, and what happens with individuals who were there for several weeks but less than 250 days. **Dr. Ziemer** mentioned that the episodic nature of testing at Pacific Proving Grounds might argue for a different approach than that used at a workplace where exposures were chronic; nonetheless, there is rationale for the 250 related to other sites where that has been the criteria based on Congressional mandates.

Dr. Neton said he could not speak to the legislatively-created SEC requirement of presence for Amchitka Island. Within NIOSH's regulation the 250-day requirement covers almost chronic-based exposures rather than discrete health-endangering short term events. Although a nuclear detonation is arguably a criticality incident, these people were removed from the blast itself to exclusion zones and their exposures due to fallout from inhalation or resuspension are classified as chronic. That was the basis for NIOSH's decision to apply the 250-day criteria.

Ms. Karo repeated her concern about how individual petitions will be treated for claimants who did not meet the 250-day criteria and asked

why Amchitka Island was an exception. **Dr. Neton** said Amchitka Island was legislatively added by Congress and he did not know why they were excluded from the 250-day requirement. As with other SEC classes, if a claimant or case does not have 250 days aggregate exposure, there would still be an attempt to do dose reconstruction using other techniques deemed sufficiently accurate. In this case, NIOSH does not have a technique to do internal dose reconstruction to the required degree of accuracy.
Ms. Karo inquired how NIOSH can proceed without the formula to figure out internal dose. **Dr. Neton** replied that NIOSH would reconstruct the external dose and if the persona did not meet the POC criteria based on external, the case would be denied.

Mr. Griffon asked for a description of the nature of these employees' work. **Dr. Neton** observed the range of activities was varied. **Dr. Wade** clarified that the people considered for this class were removed from the blast but were exposed, through their work, to radiation for at least 250 days afterwards.

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Dr. Ziemer welcomed **Dr. Paul Blake**, program manager for the Nuclear Test Personnel Review (NTPR) program at DTRA, who offered an account of how the Department of Defense (DOD) currently conducts dose reconstructions with regard to the Pacific Proving Ground and its plans for the future. The Defense Threat Reduction Agency, a combat support agency of the DOD, functions as the executive agent for DOD supporting radiogenic disease claims brought forth by former DOD personnel who participated in atmospheric nuclear weapons testing from 1945 through 1962 or served as U.S. occupation forces of Hiroshima and Nagasaki, or prisoners of war in those vicinities when the detonations occurred in 1945. DTRA supports the Department of Veterans Affairs and, to a lesser extent, the Department of Justice in evaluation of radiogenic disease claims. Since its inception in 1978, the NTPR program has accumulated a wealth of documentation associated with these nuclear events and developed methods for generating associated dose reconstructions.

DTRA has been working to overcome the technical challenges of generating dose reconstructions for atomic veterans. These challenges are well documented in the 2003 National Academy of Sciences National Research Council report that **Dr. Neton** referenced earlier. One of the consequences of the NRC report was for the Department of Veterans Affairs to return to DTRA over 1,200 previously-generated dose reconstructions for reworking and correcting challenges noted in that report.

DTRA is concerned about timeliness of the work as many veterans are elderly and do not have many years to live. DTRA has made a decision to immediately address these concerns, modify procedures and begin releasing revised dose reconstructions while also publishing articles on the revised techniques on their public web site and in peer-review journals at an admittedly slower pace. This decision has led to the current situation in which NIOSH has determined it lacks sufficient information to estimate internal doses for Pacific proving Ground personnel while DTRA is currently in process of performing that very function. **Dr. Blake** expects the problems to be resolved by the end of calendar year 2006, when DTRA's technical reports addressing the NRC 2003 report will be published.

Many of the internal dose challenges noted for the current site become even more challenging in context of the Nevada Test Site, specifically the scenario of the nuclear detonation blast wave resuspending radioactive fallout from previous detonations and complicating the determination of inhalation dose. **Dr. Blake** observed both NIOSH and this Board are in the difficult position of needing to make a timely decision, but caught in the dilemma of two federal agencies proposing two very different solutions, a challenge hopefully to be resolved by the end of calendar year 2006.

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BOARD DISCUSSION/RECOMMENDATION

Discussion began with **Dr. Ziemer** asking if the 250-day requirement applies to DTRA dose reconstructions. **Dr. Blake** explained DTRA's requirements are of a much more episodic nature; a certain time period is defined for each atmospheric atomic test, and if a person was in that area at a certain period of time they qualify. DTRA's requirements, mandated by Public Law and published in the Code of Federal Regulations, differ slightly as issued by two agencies, the Department of Veterans Affairs and Department of Justice. They can qualify someone for either presumptive or non-presumptive cancers, primarily prostate and skin cancer. Therefore, presence at even one test could rate consideration. Most of the 250,000 military personnel at Pacific Proving Ground and Nevada Test Site were part of the Navy sent there for weapons effects tests. The Atomic Energy Commission's group under consideration by this Board was smaller. **Dr. Ziemer** and **Dr. Blake's** discussion clarified that for military personnel who were closer to the detonations, external dose is the driver, whereas for the Atomic Energy Commission (AEC) personnel who were on the islands away from the blast, internal dose is more critical, yet data for these calculations are lacking.

Dr. Melius wondered if the Board's group of concern might have some workers better addressed through the veterans program. **Dr. Ziemer** thought that kind of specificity is lacking from the information database. **Dr. DeHart** asked how DTRA is handling dose reconstruction for military personnel or civilians who were in fact removed from the blast. **Dr. Blake** said internal dosimetry calculations are primarily based on radioactive fallout. **Mr. Griffon** asked about the interim rules of thumb guiding these calculations until the end of 2006 when resolution is expected. **Dr. Blake** replied that the preferable method is doing full uncertainty analysis as called for by the NRC report, but for expediency and due to large uncertainties DTRA is calculating a maximum radiation credible dose out to a 95 percent credibility limit and then forwarding them to the Department of Veterans Affairs to do the probability of causation calculation with similar software. NIOSH's challenge arises from DTRA implementation of procedures not yet published. The conservative factor of ten mentioned in statements has a statistical basis and after looking at and bounding these concepts of fractionation, DTRA considers this a good figure.

Dr. Wade commented that two federal agencies taking different positions can result from starting at different points and moving towards a common objective. He commended **Dr. Blake** and DTRA for their professionalism and commended the full vetting of issues in this debate.

Dr. Ziemer emphasized the Board's intent to give a full airing of the issues raised by differences between agencies and how things are calculated. He noted that even within the U.S. legal system, different laws can conflict so it's not amiss that not all agencies are parallel. Everyone is working together but timeliness pushes the issues. Discussion focused on the possibility of a pre-publication sharing of information by DTRA to expedite NIOSH's efforts. It would take time and possible perturbation of NIOSH's process, and not all the consequences are foreseeable, but it is possible. During the exchange it was established that NIOSH lacks specifics on the workers' living conditions, their only criteria to work with being little more than a case file, a job title in some instances, evidence of an external badge, and duration at the site. **Dr. Blake** detailed his interactions with his advisory board in preparation for their formal plan to be presented this summer in Austin, Texas.

Dr. Melius had two comments. First, he felt the need for follow-up with claimants or survivors of Amchitka Island to gather information concerning how their 24-hour exposures were weighted; these workers were given an exemption from the 250-day rule because they lived there. Second, he understands the time limits but feels the dose reconstructions in these two programs may not be reconciled because of

different legislative mandates and methods. He cautioned against institutionalizing differences between the programs and their approaches simply out of not wanting to wait a few months to get the report. The results of the SEC petition decision will last a long time and it may turn out that some of the issues used as a basis for approving it may be addressed within the next few months. Consistency is desirable. He would feel much more comfortable waiting for clarity on some of these technical issues. **Dr. Dehart** also cautioned against potentially creating two different systems for the same kinds of exposure settings. **Dr. Ziemer** supported **Mr. Espinosa's** suggestion of follow up with Amchitka Island workers to see if the 250-day issue might apply in a somewhat different way for them.

Mr. Elliott commented for the Board's consideration that at least 57 claims remain to be dealt with, some from the first batch received in October, 2001, and these claimants await a decision. He also noted that of the three with dose reconstructions, one found to be compensable had multiple skin cancers and that was done using external dose. The other two were found to be non-compensable cancers from the presumptive list.

Mr. Gibson pointed out the extensive listing of entertainment facilities at Enewetak Island which indicates workers were to stay there for extended time. **Dr. Ziemer** asked if there weren't air samples giving an idea of the levels that people on the Marshall Islands were living with every day. **Dr. Blake** affirmed that radioactive fallout was measured fairly effectively using data from film badges, actual measured fallout in water, land and biological samples. **Dr. Melius** reiterated his earlier concern, the issue of being badged or should have been badged, and possibly not qualifying people in the correct way for a Special Exposure Cohort. He felt a better and fairer job could be done using the scientific work underway for the veterans along with further work by NIOSH in describing this group of people in this cohort.

Ms. Munn expressed concern that military and civilian personnel with the same work and exposures may be treated differently since internal dose cannot be assessed. She questioned whether the DTRA process will end up being applicable for this program, and emphasized that some claimants have already waited four years. Ensuing discussion revealed that during detonations at the Pacific Proving Grounds, both AEC and DOD personnel worked together as a joint task force such that the external dosimetry records are quite consistent; however, that still does not provide a solution for internal dosimetry. It may have been the case that the military personnel were more transient than those of the Atomic Energy Commission/Energy Research & Development Administration (AEC/ERDA.) **Dr. Roessler** expressed discomfort in

lacking enough information to vote now, but was less concerned than others about the difference in agency approaches because the more critical difference resides in the types of population and their exposures. **Dr. Neton** said despite joint efforts at monitoring, the dilemma of trying to reconstruct internal dose from reconstructed external data is compounded by lack of knowing the whereabouts of these civilians.

Dr. Melius felt that it would be worthwhile for NIOSH to take the few months needed to see if DTRA's developing information would address the main technical basis for SEC determination on the issue of internal monitoring. He preferred not voting on the petition now when these concerns may be addressed shortly. He suggested asking NIOSH to address the 250-day issue by the next meeting, taking care with this circumstance in terms of qualifying these people.

A motion was made and seconded that the Board thank NIOSH for its report on the SEC petition and table further discussion to allow time for communication between NIOSH and DTRA and to address other issues previously stated by the Board.

Dr. Ziemer explained that a motion to table is not debatable. A yes vote to table will force resolution at the next face-to-face Board meeting in April. Those wishing not to table can vote no and an alternate motion could be made. However, a proposed action must first be made which could then be tabled. **Dr. Neton** pointed out that NIOSH is unlikely to have a detailed plan ready for the April meeting. **Mr. Gibson** expressed concern about the 180-day limit and wondered if waiting would gain anything.

A motion was made and seconded to accept the petition as presented.

Dr. Ziemer explained the motion to accept the petition is a motion to accept the recommendation of NIOSH to grant the SEC petition, and if it passed it would be a recommendation to the Secretary of Health and Human Services that SEC status be granted. Debate ensued.

Ms. Munn said if we can make the assumption that resuspension and internal dosimetry for individuals on those islands would vary from location to location on the islands, she believes it will be impossible to come to an acceptable conclusion on internal dose. **Dr. Melius** and **Dr. Neton** clarified that the uncertainty associated with the resuspension factor arises more from ships versus the island rather than from worker location within the islands; even so, if that is a basis for an SEC, that point needs to be captured specifically within the Board's recommendation.

Dr. Wade, Dr. Ziemer and **Dr. Blake** discussed what NIOSH and DTRA could do before the end of April that would shed light on the issue of internal exposure. With technical work still in development there is no guarantee of what the end product will look like or whether the work available in time for April will inform NIOSH's efforts, even though **Dr. Blake** believes he is authorized to share such information.

A motion to table the motion under consideration was made and seconded.

The vote was five yes to four no with one abstention. Tabling would require a majority of those voting, but the abstention is not ignored. Six votes are needed to carry the motion. **Mr. Presley** spoke to change his vote.

Upon the second round of voting, six yes votes carried the motion. The vote is to table the action until the next meeting, and it is so ordered.

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Having tabled the action on Pacific Proving Ground, **Dr. Ziemer** said the Board would need to provide instructions for its expectations within the coming week. **Dr. Ziemer** and **Ms. Liz Homoki-Titus** of HHS established that if another department provides information to HHS that is not available publicly, its degree of potential usefulness could be summarized by **Dr. Neton** or his designee without necessarily releasing classified information. If such information comes fully to the Board, however, it will be made public.

A motion was made and seconded to request that NIOSH follow up on three items in relation to this petition:

#1 to gather further information and evaluate DTRA's technical work on addressing monitoring and evaluation of internal dose;

#2 to conduct further evaluation of the types of work and nature of exposures for people in different work categories, including clarification regarding residence;

#3 to determine how best to address this issue of qualification for the cohort, i.e. monitored or should have been monitored, and possible adjustment of the 250-day requirement for full time residents.

Debate ensued. **Dr. Melius** wanted to word part three so as to ensure that this requirement makes it applicable for all the categories of

workers who might be considered for inclusion in a Special Exposure Cohort. **Dr. Ziemer** asked if monitoring for 24 hour resident workers differed from that of badged workers who left their badge at the gate when leaving a facility, and **Mr. Presley** said the badge was worn everywhere on site, 24 hours a day. **Mr. Espinosa** spoke in favor of the motion, his greatest concern being that many under the class would be denied on the basis of 250 days.

Mr. Gibson spoke in favor and **offered a friendly amendment that a member of the Board with clearance be present during discussions between NIOSH and DTRA**.

The mover and seconder accepted the friendly amendment and it was agreed that **item one of the motion would include the caveat that this be done with Board member or members present**.

The motion passed without opposition, with one abstention.

Ms. Karo was thanked and left the conversation.

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CLASSIFIED DATA:
IMPACT ON BOARD SEC PETITION RECOMMENDATION

Dr. Lewis Wade,
Executive Secretary/Designated Federal Official

Dr. Wade addressed this item as a result of the Board's questions about due process considerations. He met with representatives of both the Secretary's office and the HHS Office of General Council. The HHS position, based on a verbal opinion from the Department of Justice, concludes that non-disclosure to the public of classified information does not qualify a class for addition to the SEC if a sufficiently accurate dose reconstruction is otherwise feasible using restricted information. Therefore, HHS has no legal authority to grant a Special Exposure Cohort petition because classified or restricted information was used to determine that a sufficiently accurate dose reconstruction can be done. The Department of Justice holds that access by claimants or the public to classified information on which HHS may rely in making a feasibility determination is not required by due process considerations. **Mr. Gibson** wanted to know why the office of Legal Counsel is resistant to put it in writing. **Dr. Wade** could not answer that question but he did offer go back and ask again to get it in writing if the Board wishes. His main concern was that the Board be not limited in its ability to do its business. **Dr. Melius** argued this does disenfranchise the Board wherever there is classified or

restricted information, precluding the Board from evaluating NIOSH's review of the SEC petition. **Ms. Homoki-Titus** clarified that this simply limits public access to classified information; EEOICPA gives the Department of Energy authority to provide a grant of access to sensitive compartmented information (Q clearances) for Board members. Due to the high proportion of Board members with conflicts of interest, it was felt that the Board would benefit from having a much larger number of Q clearances.

Dr. Ziemer asked that **Mr. Gibson** and **Dr. Melius** draft a proposed motion and letter for the Board to act on tomorrow regarding its need for an increased number of Q-clearances.

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BOARD CORRESPONDENCE RESPONSE TO LETTERS FROM SENATOR CLINTON, SENATOR SCHUMER, REPRESENTATIVE HIGGINS, REPRESENTATIVE SLAUGHTER, AND MIKE WRIGHT, STEEL WORKERS

Regarding Congressional correspondence, **Dr. Ziemer** drafted some responses according to Board rules. Board members have copies of the draft response to Senator Clinton's November 7th letter concerning Bethlehem Steel.

A motion was made and seconded to accept the draft, along with proposed amendments using NIOSH's updated figures. Discussion included modification of wording, after which the motion to transmit the letter carried unanimously.

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A motion was made and seconded to transmit Dr. Ziemer's response to Senator Schumer's November 14th letter. Discussion resulted in modification of wording in the same manner as in the Clinton letter. The motion passed unanimously.

Dr. Ziemer will re-draft a response to Senator Schumer's January 19th letter requesting the Board to rescind its action of January 9. The new letter to be emailed to the Board will clarify that NIOSH's actions will come back to the Board in the revised site profile which will include more recent information such as issues raised by Mr. Ed Walker, the seeming omission of which is the basis for Senator Schumer's request to rescind.

The Board agreed without objection to look at the e-mail draft, transmit as-is if there are no wording issues or delay transmission if re-wording is needed.

It was decided that no action is needed on the letters from Congresswoman Slaughter and Congressman Higgins, as these written statements were already read into the record. **Dr. Wade** concurred. The Hanford letter will be covered during the Hanford agenda item.

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WORKER INTERACTIONS

Presentation by NIOSH/ORAU

In preparation for the letter from **Mike Wright** of the steelworkers' union, **Ms. Kate Kimpan**, project director for the ORAU team for this effort, presented a briefing on efforts with regard to collecting and taking into account worker information.

Mr. Wright's letter to the Board exemplifies a growing need felt by both ORAU and NIOSH to respond to information and comments. At ORAU's ongoing worker outreach meetings a NIOSH representative and the site profile's team leader are always present, dedicated to taking immediate action. ORAU and OCAS have developed the Worker Input to Site Profile Revisions (WISPR) database which captures all comments and assures that the commenter and public understand the team's response. **Ms. Kimpan** acknowledged there is room for improvement in coordinating the responses and conveying the value of those comments to those making them. Commenters need to know they are being heard and what is being done with the information. It's easiest to convey feedback to unions and on the web, but other methods are needed to reach individuals who may not have internet access or belong to a unified group. **Ms. Kimpan** welcomed all suggestions for improvement. For the record, this relates to ORAU Procedure 0097, Revision 00, "Conduct of the Worker Outreach Program," approved on December 29, 2005.

Dr. Ziemer requested some more formal means by which the Board could track the wealth of information emerging from the public comment periods. ORAU's Top Hat database had captured relevant information from transcripts but the Agency for Toxic Substances and Disease Registry (ATSDR)'s software package was unusable outside of ORAU. That information has been transferred to WISPR. **Dr. Ziemer** acknowledged that follow-up is occurring but felt a formalized process would

prevent comments from falling through the cracks. **Mr. Elliott** said that much of what they hear is not ultimately relevant but the people making comment need feedback on why it was not useful. Plans are underway to give SC&A access to the WISPR database. **Mr. Elliott** said written comments get a written response; verbal comments during worker outreach meetings are captured in the minutes and posted on the web; but people making comment need to be notified, appreciated, and told why the comments may not be relevant for dose reconstruction purposes. Another source of input is town hall meetings, which will be held again this summer; **Mr. Elliott** wanted that to go on record. The WISPR database does have comment and resolution; in fact, resolution is essential before an item can be closed out. **Dr. Wade** offered to make sure the SC&A task to review procedures is modified to include 0097 Rev. and at the request of **Ms. Kimpan** he will also add Revised Proc. 0031, the TBD which has been revised to accommodate these other changes. **Dr. Wade** will ask that the WISPR database be made available to the Board and SC&A and that the Board by emailed when availability is granted. Comments from this meeting should be reviewed thoroughly and entered in to the WISPR database. **Dr. Melius** questioned lack of response on comments made two years ago by union representative Mr. Glenn Bell. **Mr. Elliott** said Mr. Bell's submission included maps of the site and other information which an ORAU classification officer must review before it goes on their web site. It is under review. **Dr. Melius** emphasized the need for a formalized process to address the increasing frustration from people who sense that their comments are ignored or largely discounted. People at the sites need reassurances that significant changes will not be made without an opportunity for their input. **Mr. Elliott** and **Ms. Kimpan** agreed on the pressing need to assure people but they asserted that the comments are indeed taken extremely seriously and have resulted in many changes to actual operations for thousands of dose reconstructions. **Ms. Kimpan** will provide to the Board and the public her lengthy list of comments that have resulted in changes.

It was agreed **Dr. Ziemer** will send a formal reply to **Michael Wright** at the United Steelworkers' summarizing ORAU's efforts toward formal tracking of comments and follow up.

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ROCKY FLATS SITE PROFILE DISCUSSION/PLAN OF ACTION

Discussion of the Rocky Flats site profile matrix included remote participants **Tony DeMaiori** of the United Steelworkers and staff of the Colorado Congressional delegation: **David Hiller** from **Senator Salazar**'s

office, **Jeanette Alberg** with **Senator Allard**'s office, **Carolyn Boller** from **Congressman Udall**'s office and **Amy Warder** with **Congressman Beauprez.**

SITE PROFILE REVIEW

Mr. Joe Fitzgerald,
Sanford Cohen & Associates

The site profile review consisted of highlights of the December 15 matrix focusing on issues significant from a dose reconstruction standpoint. NIOSH will detail its preliminary responses to each of the 21 findings later, although these have not yet been discussed in the working group.

#1 The primary issue is that the use of urine bioassay MDA median values may not be appropriate for plutonium and americium, due to primitive internal bioassay techniques in the 1950's and early 1960's. They are unduly low and likely to underestimate internal dose. SC&A asks NIOSH to revisit the parameters and come up with more appropriately conservative Minimum Detectable Activity (MDAs), perhaps taking two of the four parameters and using the more extreme values to come up with higher MDA values.

#2 Another primary issue says the TBD approach to low or insoluble plutonium compounds needs review, due to the question of acute intakes of such compounds and whether or not this might be a significant contributor in certain target organs such as the GI tract. A claimant favorable approach will depend on the type of concern, per ORAUT-PROC-0003, which is not referenced in this TBD.

#3 A third primary issue addressed by SC&A is the inadequacies in neutron exposure characterization: how to extend correction factors beyond the nuclear track emulsion-type A (NTA) film energies below the 700 and 800 keV threshold and to apply such correction factors to other workers. The NTA film study focused on workers in plutonium operations. It did not include non-plutonium operations or workers possibly exposed to specific neutron sources beyond those production facilities. SC&A wants to identify correction factors that are broadly applied for neutron exposures across the Rocky Flats operations. NIOSH is working diligently to get University of Colorado's job-specific neutron exposure data.

#4 SC&A is also concerned about other issues, including addressing potential data reliability concerns; potential problems with algorithms and dosimeter calibrations; the placement of dosimeters in

relation to aprons; dosimeters not worn or not properly worn; assignment of "zero" doses at a time when everybody had a combination security/dosimetry badge. Suitable explanations for these issues are needed now to assure reliability of the data. **Mr. Fitzgerald** paused to take any questions.

In answer to **Mr. Hiller's** query about impact of unanswered questions if these issues cannot be answered satisfactorily, NIOSH would have to address that issue as a gap in the database and weigh the implications on the reliability of the overall data. **Tony DeMaiori** said the term "no current data available" was historically used at Rocky Flats for unexplained dose, even a high one. **Mr. Fitzgerald** said SC&A would be concerned about that and in fact such reports appear in the documentation from coworkers. SC&A has recommended that NIOSH look into it further.

More minor issues include concerns over the assumed default particle size of 5 micron AMAD; uncertainties not addressed for americium 241 material assay and how lung counting was calibrated with these values; the non-claimant-favorable assumption of full equilibrium in methodologies to assess internal exposure to depleted uranium; the assignment of isotropic and rotational instead of anterior-posterior geometry which may not fit some Rocky Flats workplace exposure circumstances; inadequate consideration of contaminant radionuclides present from uranium and other radionuclides shipped or processed onsite, particularly U-233 with the U-232.

Mr. Fitzgerald again paused for questions.

Dr. Ziemer pointed out to the Colorado delegation that exchanges between SC&A and NIOSH have been taking place over the past two or three months to address these issues. The Board will extend an invitation to a representative of the petitioners to take part in the face-to-face meetings. Of the six chapters in the site profile each has its own revision number; some are at Revision 1 and most are still Revision 0 in an ongoing process of updating the site profile as new information is gained.

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In the Board questions and comments period, **Dr. Wade** expressed his desire to have the Board presented with an evaluation plan before the April meeting and have the Board make a recommendation to the Secretary on Rocky Flats.

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NIOSH RESPONSE

Dr. Jim Neton,
NIOSH

NIOSH's draft responses to the 21 individual issues identified in the consolidated matrix issued in mid-December were covered in detail yesterday. Copies of the matrix are on the table. Dr. Neton's main message is that the consolidated matrix and all NIOSH efforts now will be directed towards resolving issues of specific relevance to the SEC petition at hand. **Dr. Neton** commended **Mr. Fitzgerald's** summary of the five key issues. Regarding the first two, the MDA issue and the super insoluble material, NIOSH has already come a long way towards coming to terms with SC&A and he looks forward to working with them and addressing the other issues in the upcoming working group meetings.

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Discussion Topics:

- The importance of keeping **Mr. DeMaiori** and his people actively involved in the process.
- Clarification on finding number two on the matrix, where Type S and Type M are compared without reference to super S class.
- In the analysis, super S had been determined to be synonymous with S.
- The doses to the lung are adequately covered by S because they're already more than likely over 50 percent.
- Is there a coworker model for the claimants in the SEC petition class and what percentage of the class might this affect.
- NIOSH does not typically include coworker models in the site profiles.
- Progress made toward exploring ways to validate the data.
- NIOSH is working towards that with ORAU, recognizing this will be a recurring issue.
- Whether a recommendation on the SEC petition will be ready for the Board's April meeting.
- NIOSH is working towards the pedigree of the data, providing an approach to dealing with ancillary nuclides, and example dose reconstructions.
- The reliability issue is essential because if that issue cannot be addressed then the other ones are not relevant.
- Is matrix issue nine on questions of reliability and validity of data critical in terms of the accuracy of the radiation dose.

- It is, but NIOSH is revising its response to comment number nine, as they had mistakenly addressed an internal rather than external dosimetry issue.
- The Colorado delegation is focused on that issue, and believes if there is insufficient information to determine the dose to this class, the petition must be resolved immediately.
- Premature review of an SEC petition only increases tension, wastes time and detracts from credibility of both the SEC process and overall program.

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The working groups for upcoming projects were self-selected. **Mr. Griffon** raised the concern that the current working group is becoming a standing committee, but he acknowledged that the tasks do change, so it was decided **Mr. Griffon, Mr. Presley, Mr. Gibson** and **Ms. Munn** could continue at least through Rocky Flats to function as a workgroup and coordinate with NIOSH and SC&A. **Tony DeMaiori** with United Steel Workers (USW) will represent the petitioners. For the record, Colorado delegates asked for notification of when the working group meets, and **Dr. Ziemer** agreed it will be done.

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Ms. Livia Lam, legislative assistant for **Senator Cantwell**, joined the meeting by telephone for discussion of the Hanford site profile. **Dr. Wade** reported that the only Board member conflicted on Hanford is **Ms. Munn**. She was instructed and agreed that she may participate in the table discussion but cannot make or vote on motions.

HANFORD SITE PROFILE - PRESENTATION

HANFORD SITE PROFILE REVIEW
Dr. John Mauro,
Sanford Cohen & Associates

Dr. Mauro presented the Hanford site profile review using an issues-tracking matrix as requested by the Board. Eleven issues were summarized and submitted January 16 of 2006.

#1 The major concerns have to do with neutron doses, especially in the early years, and exposures to exotic radionuclides. Neutron doses were calculated using the neutron-to-photon ratio gleaned from seven workers who had both neutron detector film (NTA film) and regular film

badges. Given the complexity and size of the site, the first question here is whether or not a seven-worker basis is good enough.

#2 Secondly, because NIOSH had been concerned that the NTA film itself was not a good detector, presumably catching only 28 percent of the exposure, they used a multiplier of 3.57. SC&A questions that adjustment factor, because the vast majority of neutrons leaving the reactor were below .7 MeV and would not register, and of the larger 0.3 particles needed to register, most would not score a direct hit to the badge. SC&A also takes issue with NIOSH's seven-fold reduction of that same neutron-to-photo ratio in the N reactor because it was based on an unsubstantiated assumption that shielding had been installed.

#3 SC&A challenges NIOSH's application of post-1972 data from the 186 Hanford Multi-Purpose Dosimeters (HMPD) to prior operations because pre-1972 there were more hands-on operations, and NIOSH's assumptions do not adjust for design and operational changes that occurred. Also, NIOSH used a dataset with measured values above 20 millirem even though the minimum detectable limit was 50 millirem.

On the issue of neutrons, **Dr. Ziemer** asked if Hanford didn't have spectral data. **Dr. Behling** said that is explained in SC&A's TBD review. The 28 percent or 3.52 correction factor for NTA film used a tissue equivalent proportional counter rather than a spectral analysis.

Dr. Neton pointed out regarding neutrons that the issue of sodium 24 doesn't necessarily mean it was an activation product in the body. There was sodium 24 in the drinking water. Regarding detection limits, he said they were generating distributions. In generating a lognormal distribution, the detection limit is not relevant as long as one is rank ordering doing cumulative probability plots. You can still pick off the 50^{th} percentile in the geometric standard of deviation. **Dr. Ziemer** was struck, he said, by the implication that they had no spectral information because he knows some of those HPs who were there in the early days and he was certain it existed. **Dr. Behling** commented on the paradox of saying NTA film was not reliable to monitor people but it's regarded as good enough to measure neutron-to-photon ratios.

Dr. Mauro continued the Rocky Flats site profile review with an overview of the issues related to internal dose. SC&A questions whether the default values capture the full distribution of recycled uranium and trace levels of plutonium, americium and neptunium in a way that accounts for all the uncertainties. Prior to 1988 the bioassay data is not great for getting a full appreciation of intakes of these radionuclides. Also, the supporting literature indicates

there was much experimental work or special campaigns involving fissile material uranium-233 and its associated uranium-232, as well as large quantities of cobalt-60, carbon-14, yttrium and polonium-210. SC&A is not convinced that the TBD addresses the rich mix of radionuclides and the associated uncertainties. Without bioassay data, surrogate approaches must be used, so how well do the instructions for dose reconstructors hold up. The TBD covers three different time periods, and **Dr. Mauro** opined NIOSH has used a pretty conservative set of assumptions; however, how reliable was the judgment of those taking air samples, considering that the full of array of radionuclides was not disclosed. Can this incredible gap for internal exposure be filled by a one size fits all measure.

Regarding lesser issues, ambiguity on instructions for interpretation of film badge data may have already been solved by use of the workbooks. Little attention was given to extremity dose. SC&A feels there is room for improvement on bounding the environmental exposure, noting that even though NIOSH used the RATCHET computer program, they did not use its puff invection modeling feature. More discussion is needed regarding exposures associated with tank farms, especially during the extensive D & D operations, along with better guidance for dose reconstructors on exposures particularly with regard to incidents. **Ms. Munn** commented on **Dr. Mauro's** refinement of the issues to a manageable size and the in-depth record-keeping continuum at the Hanford site providing a depth of information not available at all other sites. **Dr. Ziemer** spoke to assure that copies of this report will be made available.

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HANFORD SITE PROFILE /PLAN OF ACTION

Discussion followed regarding timeline targets for resolution on the work at hand.

It was decided that SC&A and NIOSH will engage in a technical discussion to which a Board member would also be invited, with SC&A to provide its transcript and summary to the Board, followed by rough draft responses from NIOSH available for further discussion.

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Dr. Ziemer requested reversal of two agenda items so the Board can hear the SC&A report before holding discussion on its own SEC procedures involving the recently developed Task Five which allows SC&A to assist the Board in various aspects of Special Exposure Cohort reviews. SC&A will be asked to review the procedures used by NIOSH and

its contractor, ORAU, on the SEC evaluation process. Subtask two asks the contractor to provide its thoughts on how the Board itself should proceed in handling SEC petitions. The working group has simultaneously developed some criteria for evaluating SEC petitions.

REPORT FROM SC&A ON SEC TASK

Subtask one
Dr. Arjun Makhijani,
Sanford Cohen & Associates

Dr. Makhijani gave a presentation on both the subtask one and two findings of the Board's contractor. They looked at the rule, 42 CFR 83 and the main procedures in OCAS PR-004 and reviewed the forms A and B which prospective petitioners would use to file the petitions, along with OCAS IG-001 and 2, external and internal dose procedures for use in SEC petition evaluation.

Noted strengths include NIOSH's logical step by step procedures allowing NIOSH to divide the proposed class into sub-classes, useful examples for early designation of a certain sub-class and dose reconstruction for non-SEC cancers.

Regarding findings, the NIOSH procedures lack detailed guidance on how to calculate maximum dose-- that is, they lack definition of criteria where maximum doses might be considered reasonable so that maximum doses do not become arbitrary, and guidelines are needed for job categories, evaluating data integrity, and for conducting a scientifically reliable maximum dose estimation for unmonitored workers.

One of the most important and difficult points arose from conflicted rules for maximum dose calculations. Maximum dose under 42 CFR 83 methods could be used to compensate as well as deny, so that should not end up being higher than the highest worst-case assumption that will involve no uncertainty under 42 CFR 82. To clarify this problem, SC&A suggests that an uncertainty which requires that the worst-case dose under 42 CFR 82 always be higher than the maximum dose under 42 CFR 83. NIOSH does have provision for working extensively with petitioners but SC&A feels that survivors who are not claimants but who may want to become petitioners need special assistance in terms of incidents, working conditions, explanation of site profiles and the like. There is post-petition assistance but more pre-petition help is needed. SC&A also recommends that a detailed interview with at least one of the petitioners be part of the guidelines, so as to obviate misunderstandings if an SEC petition is denied and to provide NIOSH with greater clarity as to the petitioners' concerns. The guidelines

could use some examples to clarify the basis for sufficiently accurate dose estimation. This advice is offered without criticism and with recognition of the benefit of hindsight. The final issue relates to health endangerment. The example in the rule and guidelines concerns external criticality accidents but there is no corresponding example for internal dose. Neither is there one for how to proceed for people who worked less than 250 days. That completed the review of the guidelines.

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In the discussion that followed, **Dr. Neton** offered clarification on what he perceives as an ongoing misunderstanding about maximum dose used to compensate or deny. 42 CFR 83 establishes the fact of the need to establish a maximum dose with plausible assumptions in order to deny a class. However, if the class were denied, that maximum dose would not necessarily be used to do dose reconstructions under 42 CFR 82; it would just be a bounding, plausible analysis to demonstrate ability to put some plausible upper limit. If a more refined method becomes available, a better estimate can be used. Without additional information, the maximum plausible dose used to deny the class could become the best estimate. At that point it is no longer a maximum dose. The maximum plausible dose for SEC petition and analysis is very different than the maximum dose used in the efficiency process to deny cases. **Dr. Makhijani** replied that the point of this finding is that whatever the terminology, a certain plausible dose method was developed as was the case of Mallinckrodt, and if that had been denied and no further information was available, doses would then have been calculated by that method to compensate or deny people, depending on POC. SC&A maintains that doses being used to deny people should be less than doses used to compensate people. There should be some restriction in going from the SEC rule after denial as to how those cases are handled, even recognizing the distinction in terms. **Dr. Neton** then conceded the point and agreed that if cases are denied based on maximum plausible, there should not be a higher maximum plausible for SEC. **Dr. Ziemer** said it is really a terminology issue. **Dr. Wade** highlighted the value of **Dr. Makhijani's** point as it relates to the Board's ability to communicate consistently with people.

Dr. Melius thinks clarification on the issue of the 250 days will come out of work on the Pacific Proving Grounds. He asked for comment on the last point, lack of procedures on determining the breadth of the class when NIOSH finds that it cannot reconstruct a claimant's dose. **Dr. Neton** agreed about the lack of such a procedure but said this is driven by the availability of the data, which speaks for itself. He said he could not envision how to proceduralize that. Discussion followed on how classes and sub-classes are intuited by sifting

through data and created through the petition process, the issue being how to recognize the right subsets to define the class and whether for efficiency that can be codified in some way. **Dr. Neton** thought that the working group's draft guidelines may help with that because they look not only at what and who was monitored but also what was not monitored. The addition of ancillary nuclides of exposure may result in definition of a class by nuclide type. Careful evaluation of data can spare the need for later re-working. **Dr. Wade** suggested inviting colleagues from the DOL who are left to make these decisions on the recommendations. This is an evolving process.

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Subtask two

Dr. Makhijani's report on subtask two contains three phases suggested for SC&A's own procedures. The preliminary step for Phase one, to be taken immediately after NIOSH qualifies a petition for evaluation, calls for NIOSH to submit an implicit evaluation plan so the review can be done serially by NIOSH and the Board. Phase two, during the time NIOSH is evaluating the petition, suggests compressing the procedure by having NIOSH provide example dose reconstructions illustrating the issues relevant to feasibility so that both NIOSH and the Board could arrive at a conclusion as to feasibility. After NIOSH has submitted an evaluation for the Board's consideration, Phase three is already in place. As delineated in 42 CFR 83, NIOSH and petitioners and all other points of view are considered for a decision on either further review or action. SC&A also suggests draft procedures by which the Board contractor can review the petition and associated documents and determine what kinds of partial dose reconstructions would be needed in order to clarify issues on feasibility of dose reconstruction. Here are their proposals for various scenarios.

1 When there is no site profile review, they would do a targeted review of the site profile only for issues relevant to maximum dose reconstructions.

2 When there is no site profile, SC&A would perform a focused review of the conditions at the site including such factors as radionuclides and job types to target what is relevant for maximum dose reconstruction under plausible assumptions for that site.

3 Partial reviews would follow steps like the ones described for phase two of the Board procedure.

Dr. Wade added that part of the task put in place with SC&A allows for the Board to ask for SC&A's assistance in a petition evaluation review, whether it be a full or task-specific review.

During the comments, **Dr. Melius** said he'd prefer to use the term targeted rather than partial. He suggested that after reviewing the materials, NIOSH could prepare a more specific plan for what they regarded as the critical datasets, particularly regarding the SEC evaluation, to be discussed at a meeting with NIOSH, a workgroup and the contractor. This approach would be parallel rather than serial. **Dr. Ziemer, Mr. Griffon** and **Dr. Melius** brought forth that this is already happening to some extent, but the current terms such as partial, full, and targeted can be confusing in context of the SEC review. **Mr. Elliott** acknowledged that the plan given today and on every evaluation of a petition is intentionally generic and hopefully comprehensive in its generality. It's a struggle within the 180 day time frame to provide a scientific basis for making a recommendation to add or deny a class. Rather than provide a make-work, additional detailed plan, he can see better benefit in a coordinated effort involving NIOSH, the working group and SC&A, meeting to discuss the salient issues for evaluating a petition. **Dr. Mauro** noted that the closeout process, for which his team allocates 150 hours, has now become part of the much more demanding SEC process. **Dr. Makhijani** supported the need for more site-specific information from NIOSH, particularly on dose reconstructions for SECS in conjunction with site profile reviews. Feasibility under SEC requires that the methods be actually applicable in real dose reconstructions. The other big difference is that in site profile reviews, vertical issues are highlighted but not covered in detail, whereas for the SEC petition review, every detail on feasibility must be covered for the answer on all cancers and all members of the class. He feels there is great merit in having something focused on SEC reviews.

Mr. Griffon echoed the spirit of the intent to have earlier involvement with the Board and SC&A rather than a detailed plan which could become obsolete within the 180-day limit. **Dr. Makhijani** made assurances there is no bureaucratic intent in their proposal. **Dr. Melius** said NIOSH does have access to information that is available to no one else -- completed dose reconstructions for a particular site, which would be helpful in developing a more focused plan earlier in the process. **Mr. Elliott** agreed on the benefit of that. NIOSH is taking seriously the Board's need to see example dose reconstructions if NIOSH is saying to deny the class. **Dr. Wade** said the discussion has been useful and he thinks the spirit of **Mr. Elliott's** suggestion is the same as those presented by **Dr. Makhijani**. To facilitate the process of earlier interaction, he pointed out the Board's opportunity now to choose one site to use as a first example of trying to put this

process in place, as the current targets of opportunity are limited. From the standpoint of limited resources, **Mr. Elliott** asked the record to show which site petitions are currently being evaluated. They are the Pacific Proving Ground, the Rocky Flats petition, Chapman Valve, the Oak Ridge Institute for Nuclear Studies -- almost all of the ORAU folks are conflicted there so his group is doing that, which presents yet another resource-limiting problem -- and Ames, Iowa. **Dr. Ziemer** suggested completing the framework for that decision today and then making a specific site choice tomorrow.

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PROCEDURES FOR BOARD EVALUATION OF SEC PETITIONS
DISCUSSION PART II
(including pending Y-12 Petition and SC&A SEC Task)

Concerning the item called procedures for Board evaluation of SEC petitions, **Dr. Ziemer** felt this was the time to identify any substantive changes to the document. **Dr. Wade** reminded the Board that the Secretary wants full vetting of the document along with the opportunity to comment on the procedures before they are finalized by the Board. **Dr. Melius** began the discussion listing issues raised yesterday: feasibility, timeliness, regulations, and use of data from other sites for a site profile. **Ms. Homoki-Titus** could not at this point give a legal interpretation of timeliness, but she read a portion of the actual statute which uses the term and cited the two new deadlines that have been added, the 180 days to make a recommendation and 30 days for the President to provide a determination to Congress, once this Board provides a positive determination to the Secretary. She also stated that the current and recommended SEC rule gives the Director of OCAS the ability to determine that records are not available in the timely manner. **Ms. Munn** spoke for accepting the document as is, explaining that specificity will reduce both fluidity and timeliness of the process. She offered to move it. **Dr. Melius** first wanted to come up with criteria for how to use data from other sites. **Dr. Ziemer** suggested accepting the document provisionally, soliciting input from the Secretary’s office and having a caveat that it’s open to additional amendments as the Board sees fit.

A motion was made and seconded that the Board accept the document before it as a provisional document, with the understanding that the input of the Secretary's office will be used to help expand the document and complete it. The motion carried unanimously.

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PUBLIC COMMENT

Dr. Ziemer greeted attendees for the Public Comment period and explained what the Board does and does not do.

The following is a list of the members of the public who spoke. A full transcript of the public comment is available on the OCAS web site, www.cdc.gov/niosh/ocas.

Mr. Jim Phelps, son of Y-12 employee; Mr. T. L. Dishman, retired Y-12 employee; Mr. Ray Beatty, Fernald employee; Ms. Johnnie Sue Goodman, survivor wife; Ms. Helen (last name not given), survivor wife; Mr. Franklin Tucker, retired Y-12 employee; Ms. Dorothy Thompson, Y-12 widow; Mr. Thomas Duncan, claimant; Mr. Paul Royster, son of Y-12 employee; Ms. Florene Robertson, X-10 widow; Ms. Gail Burgess, survivor daughter; Ms. Sharon Slackey, survivor daughter; Ms. Kathy Miller, survivor daughter; Ms. Faye Holt, survivor wife; Ms. Lindsay Long, claimant; Mr. Earl O'Neal, former Y-12 employee; Ms. Diane Boinet, survivor sister; Ms. Shirley Moody, Y-12 widow; Mr. Dennis Brown, K-25 survivor ;Ms. Diane McKeethan, claimant; Mr. Frank Scott, Y-12 employee; Ms. Valerie Maner, daughter of Y-12 employee; Ms. Ellen Foster, claimant's daughter; Ms. Janice Allen, claimant's daughter; Mr. M. L. Russell, claimant; Mr. Otis Lee, retired DOE employee; Ms. Debra Kiley, survivor daughter; Mr. Martin Delozier, claimant's son; Mr. James Hackworth, brother of former Y-12 employee; Mr. Leonard Bowers, retired Y-12 employee.

With no further comments, the Board officially recessed until the following morning.

Thursday, January 26, 2006

Dr. Ziemer opened the third day of sessions on the Advisory Board on Radiation and Worker Health, reminding all to register attendance and pick up a copy of the agenda and related documents. **Mr. Elliott** read a written statement into the record on behalf of Ms. Beulah J. Lindsey and her brother Alvin, who could not stay for last night's public comment session. That statement appears in the transcript of the meeting available on the OCAS web site, www.cdc.gov/niosh/ocas.

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In his conflict of interest statement **Dr. Wade** said that for Nevada Test Site the only conflicted person would be **Mr. Griffon** when dealing with an action filed by building trades union. For Savannah River Site there are no conflicts.

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STATUS REPORTS AND DEVELOPMENT OF PLANS FOR SITE PROFILE REVIEWS - NEVADA TEST SITE, SAVANNAH RIVER SITE

Nevada Test Site Profile Review
Dr. Arjun Makhijani,
Sanford Cohen & Associates

Dr. Makhijani gave a first look and status report of the two preliminary site profile reviews now underway, Nevada Test Site and the Savannah River Site, for which matrices have been submitted. Revision 0 has been reviewed and Revision 1 is in the works. Regarding major internal dose issues, the review found there is no internal monitoring data until late 1955 or 1956, and NIOSH has not published a method by which those doses would be estimated. Radionuclide lists are incomplete particularly regarding short-lived radionuclides. The site profile recommends use of Technical Information Bulletin 002 for post-1971 tunnel re-entry workers although the TIB itself says it is not to be used for that purpose. Currently, photon doses are used to estimate internal doses, raising issues on data integrity and large hot particle. Data integrity is in question due to the apparent practice of some personnel removing their badges so as not to exceed the quarterly dose limit thereby keeping themselves eligible for the high pay offered for working in forward areas.

SC&A's review questions correction factors used for external dose in regard to badge location and job locations. The assumption that atmospheric test workers were not exposed to neutrons is unvalidated. Although it is true that most workers were kept well away from the tests, there were pressures to put personnel in forward areas. Large hot particles greater than 10 microns could wind up in the GI tract, a situation which **Dr. Makhijani's** team feels would be complicated by oro-nasal breathing of non-respirable particles. Extensive Naval Radiological Defense Laboratory (NRDL) research on the issue of large hot particles was cited in the site profile but not discussed. **Dr. Makhijani** offered a correction; the matrix should read "venting of underground tests" not atmospheric tests.

The review found many issues regarding environmental dose; these methods and models could significantly underestimate the environmental

dose by an order of magnitude or more. The resuspension model used in the site profile is appropriate only for early re-entry within weeks or months but not re-entry after years. Fractionization of radionuclides, in which non-volatile radionuclides are deposited closer to the test site and volatile radionuclides travel farther, needs to be taken into account in environmental dose calculations. Gaps in extrapolations in the environmental dose record were not deemed appropriate.

The Nevada Test Site is admittedly complicated but in some essential respects the record review and interview process was not complete, resulting in gaps in the site profile. The review team was told that in interviews, NIOSH only records what it considers important, whereas the importance of information is not always evident until later, so better documentation of site expert interviews is required. Other major issues include radon issues for G-tunnel workers, the status of the Gravel Gertie workers, and lack of discussion of radon dose issues.

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DEVELOPMENT OF PLANS FOR NEVADA SITE PROFILE REVIEW

Questions and comments on the Nevada Site Profile review presentation followed. **Dr. Makhijani** said the information about badges not being worn came up in two independent site expert interviews. There are a whole set of documents validating these kinds of employment practices. **Dr. Ziemer** mentioned that before the late 1950's, lifetime doses were not kept. Only weekly limits were noted. **Dr. Makhijani** said the introduction of the integral identification and film badge in 1966 may have helped alleviate the situation, but more research is needed. Workers in forward areas were given hazard pay.

Dr. Neton expressed his appreciation for SC&A's consolidation of the report to manageable significant issues. On the monitoring issue, he said he's seen that workers without badge results continued to have tritium excreted from the urine, a detail which supports SC&A's contention that badges were often removed. **Dr. Ziemer** said that would be another good way to cross-validate. NIOSH recognizes the gaps in the site profiles and is for that reason moving very cautiously with dose reconstructions at Nevada Test Site, particularly during the above-ground, atmospheric testing era.

Dr. Makhijani clarified to **Dr. Roessler** that the radon accumulation owed not to the soil, as at Iowa, but to the enclosed structure at Nevada. Speaking from the audience, **Mr. Mike Molino** did not reveal his affiliation, but interjected he has been to the test site numerous

times and could attest that a Gravel Gertie was used for cover at Nevada Test Site for seven balloon shots during the early years.

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SAVANNAH RIVER SITE PROFILE REVIEW 2

Dr. Makhijani presented the Savannah River Site Profile Review 2, completed in October of 2004, explaining that SC&A has not yet reviewed NIOSH's Revision 3 published April 5, 2005, so some of the issues to be addressed here will likely have already been resolved. Recycled uranium was one issue. Coverage of radionuclides from the transplutonium coverage needs to be fuller; exposure to cobalt-60 and an array of other radionuclides need to be considered. Dosimeter calibration is on normal incidence, so the question of exposure angles needs consideration. Dosimeter adjustment factors used in the Savannah River site profile are not consistent with the DOE complex-wide recommended factors. Some familiar neutron-to-photon ration and neutron dose questions are at issue. The geometric mean and standard deviation is not technically defensible or claimant-favorable. Variations of these ratios within a given facility, such as the FB-line, need to be taken into account. SC&A recommended use of the 95th percentile values for the period where there are TLND neutron dose data.

There was an incomplete characterization of the Tank Farms. Many of the spills were not entered into a databank. Exposure from ground spills relative to badge location could be important. These are significant issues and it's important to try to establish a complete list of incidents. This review also details inadequacies in the early internal and external monitoring programs.

Coworker models for early workers have not been developed. Some recorded intakes were higher than the high five, so the high five seems not always to be an actual high five. There seemed to be an inconsistency with the regulation 42 CFR 82. There's an assumption that the high five approach is necessarily the worst-case approach. Various factors led SC&A to conclude that its use may result in a very high overestimation of the dose in most or all cases, but it is not clear this could be demonstrated given the present state of the documentation reviewed.

SC&A also questions the applicability of an off-site source term to on-site exposures; it may be appropriate in some but not all situations. The review finds a need to improve internal dosimetry with regard to radionuclide solubility. Some sources of external dosimetry are not being used in the dose reconstruction process. Special

exposure circumstances for subcontractors and construction workers need to be considered.

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In the discussion on this review, **Dr. Makhijani** agreed to provide information on additional external dose dosimetry to the Board and NIOSH via e-mail. **Dr. Ziemer** and others attended to wording in the minutes regarding a motion and agreement to hold a face-to-face session on development of the matrix. It was decided that the minutes need to be reworded to indicate it was not an official response. **Dr. Ziemer** did want the Board to be aware that there was an action already in place in moving forward on the resolution process, this matrix being the first step. **Dr. Wade** commented that the Board has a great deal on its plate and the group must keep the entire field of play in view so that other priorities such as SEC petitions do not stop progress on any project. He suggested talking about a possible course of action for the Nevada and Savannah River Test Sites.

Dr. Ziemer conducted the formation of workgroups and team leaders for each site. (Team leaders are listed first.) Nevada Test Site: **Presley, Clawson, Munn, Roessler**; Savannah River Site: **DeHart, Gibson, Griffon, Lockey**; Hanford Site: **Melius, Clawson, Poston,** and **Ziemer**. **Dr. Mauro** offered to prepare a revised matrix that reflects Revision 3. Without objection, the contractor was ordered to proceed along those lines.

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CONFLICT OF INTEREST DISCUSSIONS

Dr. Lew Wade, Executive Secretary

This issue was initiated by a February 20th, 2005 communication from **Mr. Richard Miller** to **Dr. Neton** at NIOSH and **Dr. Toohey** at ORAU, raising issues about the Paducah site profile conflict of interest issues and also technical issues. A contract oversight team issued a report dated October 11, 2005. It was made available at the last Board meeting, although not discussed. In light of that report, on December 9 **Mr. Miller** corresponded further with **Dr. John Howard**, Director of NIOSH, and **Mr. Michael Leavitt**, Secretary of HHS, a copy of which was provided in the Board members' packets. **Dr. Howard** responded to **Mr. Miller** on December 29. As **Mr. Miller** requested, **Dr. Howard** took a personal interest in this issue, in this case as it relates to the ORAU contract. The two basic issues are conflict of

interest issues as currently embodied n the draft policy for ORAU, and the technical issues raised by **Mr. Miller** regarding the Paducah site profile. **Dr. Wade's** suggestion for a format addressing these concerns was accepted by **Dr. Ziemer.**

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Mr. Elliott began the discussion, explaining he commissioned the October review by the assessment team of **Mr. Michael Rafky** out of the Office of General Counsel on the NIOSH radiation legal team; **Ms. Lauri Ishak**, a Presidential management fellow at NIOSH; and **Mr. Robert Daniels**, a health physicist with NIOSH. Their charge was to evaluate the concerns raised in the February 20 letter to **Dr. Toohey** and **Dr. Neton** and determine whether a conflict of interest (COI) policy violation occurred during the development of the TBD for the Paducah Gaseous Diffusion Plant and whether or not data was purposely excluded that should have been incorporated in that site profile. The findings of that report are so stated.

The conflict of interest policy employed during the approval of this site profile was found to contain ambiguous language. In the interim, this Board raised concerns and ORAU complied with the need to make a change in their conflict of interest policy to address site profile development. Violation of the then-current COI policy did not occur. Although the language was ambiguous, the assessment team felt that the underlying intent of the policy was followed.

Besides ambiguous language, the team identified lack of clear definitions of roles, responsibilities, and terms such as subject expert, document owner, and primary author. Regarding the technical basis of the Paducah site profile, concerns were raised that the subject expert did not include a careful consideration and inclusion of all data, such as data on ash receivers in the pulverizer area, into the presentation of information in the site profile.

The revised policy as presented today provides much clearer explanation and definition of roles and responsibilities and clear definitions of terms such as conflict and bias. It identifies clearly what the review process is and what level of attribution and disclosure is required.

Ms. Kimpan was invited to speak on this. She expressed pride in the work that ORAU is performing for NIOSH on behalf of sick workers and said this issue is important to ORAU. It goes to ORAU's credibility, public standing and the quality of the work. Full disclosure is paramount. ORAU fully embraces and is implementing this policy even in its draft form. ORAU is following the full spirit of the policy, which

is that no one who is in a potentially or actually biased or conflicted role will be a document owner for any part of the work.

Mr. Elliott added that his group feels so strongly about this policy and its clarity and comprehensiveness that once ORAU finalizes it, it will be modified to become the OCAS policy. The policy itself requires NIOSH approval. **Mr. Elliott** welcomes Board input also.

Board members expressed a need for more time to digest the information before taking action on it.

The dearth of experts in this field could lead to conflicts of interest. Proper attribution, transparency and objective, scientific criteria will be used to minimize the potentially compromised effect of having such a small pool of qualified site experts. **Mr. Elliott** elected to read the definitions of key distinctions from the draft.

Offered an opportunity to speak, **Mr. Miller** said conflict of interest taints the science that comes out the door and all associated organizations. He opined that this Advisory Board is here today with NIOSH doing this work because Congress found they couldn't rely on the Department of Energy to do it. The burden is on this conflict of interest policy to have adequate checks and balances due to the paucity of a pool of available experts. He suggested conflict of interest is not merely financial, as outlined in the newly proposed draft. It involves organizational and professional conflicts of interest, both of which are omitted from this policy. He urged his listeners to treat the draft as a work in progress. He agreed to provide his ten-page white paper to **Dr. Wade** for the Board. It lays out in detail a critique of the October conflict of interest draft policy and provides, in a side-by-side analysis, guidance on what the new policy ought to look like.

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PADUCAH SITE PROFILE/TECHNICAL ISSUES

Mr. Stuart Hinnefeld,
NIOSH

Numerous items of a technical or scientific nature prompt additional investigation. A recent data capture including early documents speaks to this issue -- the analysis and identification of non-uranium contaminants in the uranium materials in various places. NIOSH has instructed ORAU to synthesize this and give NIOSH the best product available in light of this discussion.

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Discussion Points:

- This issue should be resolved quickly for the credibility of the program.
- A plan for NIOSH to develop a procedure for investigating any conflict of interest issues that arise.
- NIOSH staff is being put in the difficult position of investigating themselves.
- Need for an outside involvement mechanism for evaluating the portion of COI situations that pertain to NIOSH.
- Should SC&A also review the revision of the Paducah technical document.
- **Dr. Howard**'s letter requests the Board undertake review of the technical quality of the document.
- The entire document should be reviewed to ensure corrective action called for in the assessment report was attended to in the revision and all technical information was provided in a new revised site profile.
- Conflict of interest addresses perception, as well as technical or legal violations, and even the possibility of a conflict needs to be addressed.
- Perceptions may or may not be valid, such as the assumption that the individuals who know most about a topic are the ones to be least trusted.
- A need for management to be up front about possible perceptions and state how the issue is being handled.
- The importance of transparency and how disturbing that conflict of interest statements have not been consistently made available.
- Concern about the terminology limiting conflict of interest to financial interest.
- The policy is written to fit how ORAU works and is not easily understood by people outside that group.
- Conflict of interest training for federal agencies focuses on financial conflicts, while this program is more concerned with programmatic and related issues.
- This proposed policy applies to every aspect of ORAU's operations.

Following **Dr. Ziemer**'s call for a motion to delineate the task to be undertaken in response to **Dr. Howard**'s request for Board review, **Dr. Wade** announced the only Board member conflicted on the Paducah site was **Mr. Leon Owens**, who was not present at the meeting.

A motion was made and seconded that the Board give SC&A the task of reviewing the revised Paducah site profile, with particular attention to the issues raised in Mr. Miller's February 2005 letter, as well as in the NIOSH assessment of the conflict of interest issues related to the original site profile.

Following discussions related to timing and slowing down work on other sites, the sense of the motion was refined to reflect that the work would get underway at such time as the materials are available, and that the Board will be kept apprised of the status. Even if there is a delay of a couple of months to fit the work in, there should be no dropping of current plans as this becomes additional work.

With that clarification, the motion carried unanimously.

Further Discussion Points:

- ORAU's intent to apply the policy retrospectively.
- It applies to things not actively in the review process, as well as what is in the formal review process.
- The need to keep Board members and the public informed when a change is made on a site profile.
- An obligation to follow up on changing disclosure statements, with ORAU making assurances of full status updates and transparency.

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TASK III REVIEW – DISCUSSION/CLOSURE

Mr. Griffon gave an update on Task III, the review of the procedures task. On Tuesday, the subcommittee, having previously reviewed the procedures related to external dose, reviewed the procedures focused on internal dose and the CATI interview procedures. Any comments not agreed upon in the NIOSH response column of this matrix were pushed into the workgroup process for in-depth discussion. They want to cross-walk any procedures that have been replaced to be sure none were lost. At behest of the Board, **Dr. Wade** amended the contract to see that OTIB-4, the latest release, is added to the list; ORAU-0097, Rev. 00; and ORAU-0031. These will be added to the new list or procedures to review that is already in place. When it is completed, **Ms. Behling** will e-mail to the Board the list of new procedures containing information on where there are workbooks associated with the various documents. **Dr. Mauro** said work and assignments on the originally authorized 33 procedures has begun, but they have found that some of

those do not need review and some have already been reviewed so he will transmit to the Board a recommendation for replacements and additions and the reasoning behind them. **Mr. Griffon** hopes to finalize these internal dose and CATI interview resolutions at the next workgroup meeting, date yet to be set so a determination of the scope can first be made.

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INDIVIDUAL DOSE RECONSTRUCTION REVIEWS

Mr. Griffon summarized the status of individual dose reconstruction reviews. The Board has closed out on the first set of 20 cases and the Board's acceptance letter is drafted and hopefully en route to the Secretary of the HHS. It will also be posted on the internet. The second set of 18 is the next case review item for the workgroup as they have not had a chance to review NIOSH's responses. NIOSH has just received the findings for the third set of cases so time is needed for their response, and SC&A has competed reviews on the fourth set and is ready to do the team conference calls with the groups for which new assignments are needed.

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REVIEW AND APPROVAL OF BOARD MINUTES

Discussion was held on minutes for the August 2005 meeting. **Dr. Ziemer** noted that although the minutes are abbreviated from transcripts, the motions themselves should be full and complete.

A motion was made and seconded that the minutes for the August meeting be approved as modified. The motion carried unanimously.

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It was agreed the minutes for the October meeting would be modified to add **Mr. Leon Owens**' name to the list of attending Board members.

A motion was made and seconded to approve the minutes for the October meeting as modified. The motion carried unanimously.

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BOARD WORKING TIME
Recognition of Departing Members
Future Meetings and Plans

Dr. Ziemer formally recognized the careers and contributions of two outgoing Board members, **Mr. Richard Espinosa** and **Dr. Henry Anderson**. Both were awarded a certificate of recognition from the HHS and a letter signed by **Dr. Julie Gerberding**, Director of the CDC, and **Dr. John Howard**, Director of NIOSH.

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Ms. Kimpan updated the group on her response to a substantive concern raised this morning concerning a new disclosure form that had less information that the prior form. She tasked her people to check for consistency of the first and second forms. Information is being corrected on the ORAU web site.

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SEC RULE REWRITE

Mr. Ted Katz,
NIOSH

Dr. Wade proposed options for dealing with the rule comment period closing February 21. He asked **Mr. Ted Katz** to describe the changes for elucidation only.

As background, **Mr. Katz** explained that in December 2005 HHS published amendments to its Special Exposure Cohort rule. That rule is presently open to public comment until February 21st, but was made effective immediately as a provisional rule and open to changes on the basis of public comment before it is finalized. He read verbatim Section 73.84(q)(c), the rules on deadlines. Two changes were made to make it compliant with new statutory requirements. The first was to establish the definition of a petition in the rule. Under 83.8 it means a submission that meets all the requirements and has incorporated any revisions made and added any material needed for the petition to qualify.

After a petitioner works with NIOSH and submits a petition and makes whatever revisions are needed, if the petition still doesn't quality at the end of that process, NIOSH notifies them and they have the right to request a review of that decision. Previously there was a 30-day period to request that review. The second change reduced that period to seven days.

The reason for the change is because the 180-day counting period for action on the petition is based on when the petition met the

requirements and became a proper petition. In the event NIOSH determined the petition didn't qualify and the petitioner's appeal for review determined NIOSH to be in error so that the petition had actually qualified earlier, the period of time expended on appeal and review would have eaten into the 180-day period for evaluation. This is important because the time constraints are already great.

Another provision is regarding the finding of feasibility and health endangerment. After a petition is evaluated and the Board has made a recommendation and there's been a proposed decision by the Director of NIOSH, the petitioner had an opportunity to seek a review of that proposed decision. However, the 30 days allotted wouldn't allow for the petitioner to bring the request, let along do the review and come to a final decision. That has now been moved to the end of the process and the Secretary will make final decisions. However, those decisions will have the same review rights the proposed decision had before.

Additionally Congress is requiring a report of both affirmative and negative decisions or determinations. And finally Congress has changed their 180-day period to review the Secretary's proposals to add new classes to 30 days, so that change is included in the rule. The Board devoted considerable discussion to the reduction of a petitioner's review request time to come to a full comprehension of what this means in terms of process and fairness. It was decided that the language is not clear. Five issues of strong concern over this rewrite emerged, including the 7-day petitioner appeal, the meaning of timeliness, the interpretation of the 180-day limit and the issue of the time frame to qualify. **Dr. DeHart** suggested that a lead be appointed to gather the proposed comments, and **Dr. Melius** volunteered. **Dr. Ziemer** suggested he put together a categorized response for Board consideration prior to a conference call. Without objection, the Board will follow that pattern with **Dr. Melius** having the lead.

It was then decided to request extension of the public comment period past March 14th, at which time this will be one of the items for the Board phone call scheduled for that date.

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Dr. Melius read into the record his proposed letter for the Department of Justice concerning the Board's desire for written legal advice while maintaining a process consistent with the original intent of the EEOICPA legislation.

A motion was made and seconded that the subject letter be sent to the Secretary of HHS.

Discussion followed, during which the wording rather than intention of the letter seemed to be at issue; Board members were concerned about how to express, acknowledge and work with the fact that petitioners may want what is in fact classified information.

The letter was amended to include the comment that "While the Board is fully supportive of the need for preventing the release of classified or restricted information and recognizes the necessary use of such information in the DOE nuclear program, the Board also recognizes.." With that change, the motion carried.

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TASK III REVIEW - DISCUSSION/CLOSURE

The Board entered discussion to formulate its decision on Task III concerning assignments to make to the contractor on their SEC petition evaluation task. Participants clarified the status of various site projects, terminology for the work to be done and its relation to SEC work now underway, the nexus of SC&A's involvement with NIOSH in terms of timing and series or parallel efforts, options for the tasking procedures, consideration of personnel resources given time constraints, the formation of workgroups for the various sites, and the spirit and intent of Task III. It was determined that Y-12, Rocky Flats and Ames, all of which have qualified SEC petitions, are the most suitable choices for concurrent additional work by SC&A due to their upcoming 180-day deadlines and relative clarity of issues for SEC petitions at the first two. Site profile work and SEC petition questions can be addressed concurrently and efficiently by early information sharing between SC&A, NIOSH and possibly a workgroup. The workgroup assignments include **Mr. Griffon's** workgroup for Y-12 and Rocky Flats and a new workgroup for Ames including **Dr. Melius** as chair, **Dr. Lockey** and **Ms. Munn**. **Dr. Wade** summarized by saying he would deal with the contracting officer to issue three tasks under the SEC task of the SC&A contract. One will be a total review of Ames. The specific action there will be to schedule a meeting of NIOSH, SC&A and the Ames workgroup, respectful of peoples schedules. Also, two task orders will be ordered for focused SEC reviews for Y-12 and Rocky Flats, and the substance of those will be the opened issues identified by the workgroup in the high priority matrices.

Mr. Griffon asked if the Board will be asking SC&A to assist with Pacific Proving Ground. **Dr. Ziemer** said **Mr. Presley** has volunteered to

represent the Board at the meeting with DTRA. **Dr. Neton** will FedEx a copy of the Y-12 CD data to the working group and SC&A; there is no problem in sharing it under the provisions of the Privacy Act. SC&A will have it in case the workgroup needs to ask their assistance for the meeting tentatively set for February 27th. **Dr. Melius** made the point that Task V authorization requires direction. **Dr. Wade** clarified that any immediate work can be done under the site profile task and he will work with dispatch to get an SEC focused task for Y-12 that will cover the continuation of work. **Dr. Mauro** commented that during the presentations of Rocky and Y-12 it's not always apparent which of the items represent site profile issues. One of the big challenges in streamlining and expediting the process will be to quickly come to a common mind regarding which issues are SEC issues so a focused assault can be designed. He didn't know if there would be universal agreement right now if a discussion were held on this matter. He has a clearer idea of what he believes to be SEC issues on Rocky Flats than on Y-12. **Dr. Wade** said he'll take his lead on that task order from the chair of the working group and then dialogue with **Dr. Mauro**, who expressed his sense that the process will involve a great deal of iteration because the investigations will lead to a point where it's believed a dose reconstruction can be done but they do not know exactly how to do it. It will be a matter of identifying SEC issues as clearly as possible and agreeing on what degree of conservatism can be used.

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PROGRAM UPDATE -- NIOSH

Mr. Larry Elliott, Director
Office of Compensation Analysis and Support

Mr. Elliott presented NIOSH's program and science issues updates according to the slide presentation and handouts. He reported the completion of 12,264 draft dose reconstruction reports as of January 13, 2006, although he wished they could have done more. The number of active claims, 486, has changed since January; all these numbers are fluid. Of note are the proposed changes to the target organ for reconstructing dose for lymphoma cases about which the Board approved a draft of this OCAS TIB on January 9th. The comment period closes February 4th, he believes. About 1,000 claims will be affected one way or another by this change. **Mr. Elliott** is working closely with **Ms. Kimpan** on making sure comments from the public comment period are being addressed, and she in fact will be following up on items from this Board meeting tomorrow. He noted that NIOSH still takes many claimant and stakeholder phone calls as well as e-mails, to which they try to respond within 24 hours. There were no questions.

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PROGRAM UPDATE -- DEPARTMENT OF LABOR

Dr. Diane Case,
Department of Labor

Dr. Case's statistics were represented on her slide show and handouts. She elucidated on the terms claims and cases. A case refers to an individual employee's case, which can contain more than one medical condition and have one or more claimants on that, the survivors. Most of the claims they receive are for conditions that are non-covered. The next majority of claims they receive are for cancers.

After her presentation, **Dr. Melius** commented on the difficulty of communicating these programs to the claimants, who have been told it's an easy process with NIOSH ready to assist them. Once they get into Subtitle E program, they suddenly have to produce a great deal more information on disabilities as well as sometimes on medical and exposure. He wondered if anything can be done to facilitate the process beyond the town meetings. He also wanted to put on the agenda for the next meeting the issue of how to deal with the non-SEC cancers, such as determining when it will be feasible to reconstruct certain types of cancer and certain exposures in the situation where we are also approving a Special Exposure Cohort. It's tricky and could create a lot of unnecessary work. Finally, he wanted to be sure that future presentations include the number of cases coming back from the DOL to NIOSH for reworks so any potential problems in the program can be addressed. **Dr. Case** replied that her rough estimate is 450. A small percentage get through that never should have gotten through and they were fine, but a majority of them have to do with the claimant not bringing information forward after the dose reconstruction has been performed. She will be sure to include that information in the next presentation.

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In the spirit of transparency, **Dr. Wade** made an update that in the fourth round of reviews by SC&A they identified three cases where overestimating assumptions were used in error which could possibly impact compensation decisions, so the cases will be re-opened and re-evaluated. He will keep the Board posted. He thanked SC&A for that effort and felt it indicates the benefit of the audit program. **Dr. Ziemer** clarified that although the audit is not intended to be a process for reopening claims, if something is identified that could

have a significant impact, it is prudent that the contractor at least alert NIOSH to this as soon a possible before the review process has been completed. This type of early alert, although not covered in procedures per se, exemplified the intent to identify systemic issues and process procedures.

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Scheduling plans were announced for a March 14 phone call at 10 a.m. Eastern time which will include new Board members; the face-to-face Board meetings April 25, 26 and 27; other Board meetings to be set for June and early October. Board members will be contacted with exact dates once the new members are fully vested and clearances complete; a phone call in between the face-to-face meetings to deal with items requiring immediate attention. **Mr. Griffon's** workgroup meetings are scheduled for February 13th, 9:00 to 4:00 in Cincinnati for a procedures review, the second and third sets of cases; February 27th 9:00 to 4:00 for Y-12 and Rocky Flats SEC. Because those meetings will be open to the public and not held in NIOSH's offices, **Dr. Wade** suggested that the other chairs of working groups look at those dates and consider combining meetings to simplify logistics since a hotel facility will need to be secured. He agreed to e-mail dates and committee information to everyone.

Dr. Ziemer adjourned the meeting at 4:05 p.m.

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With no further business to come before the Board, the meeting was adjourned.

End of Summary Minutes

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I hereby confirm these Summary Minutes are accurate, to the best of my knowledge.

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Paul L. Ziemer, Ph.D., Chair

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Date